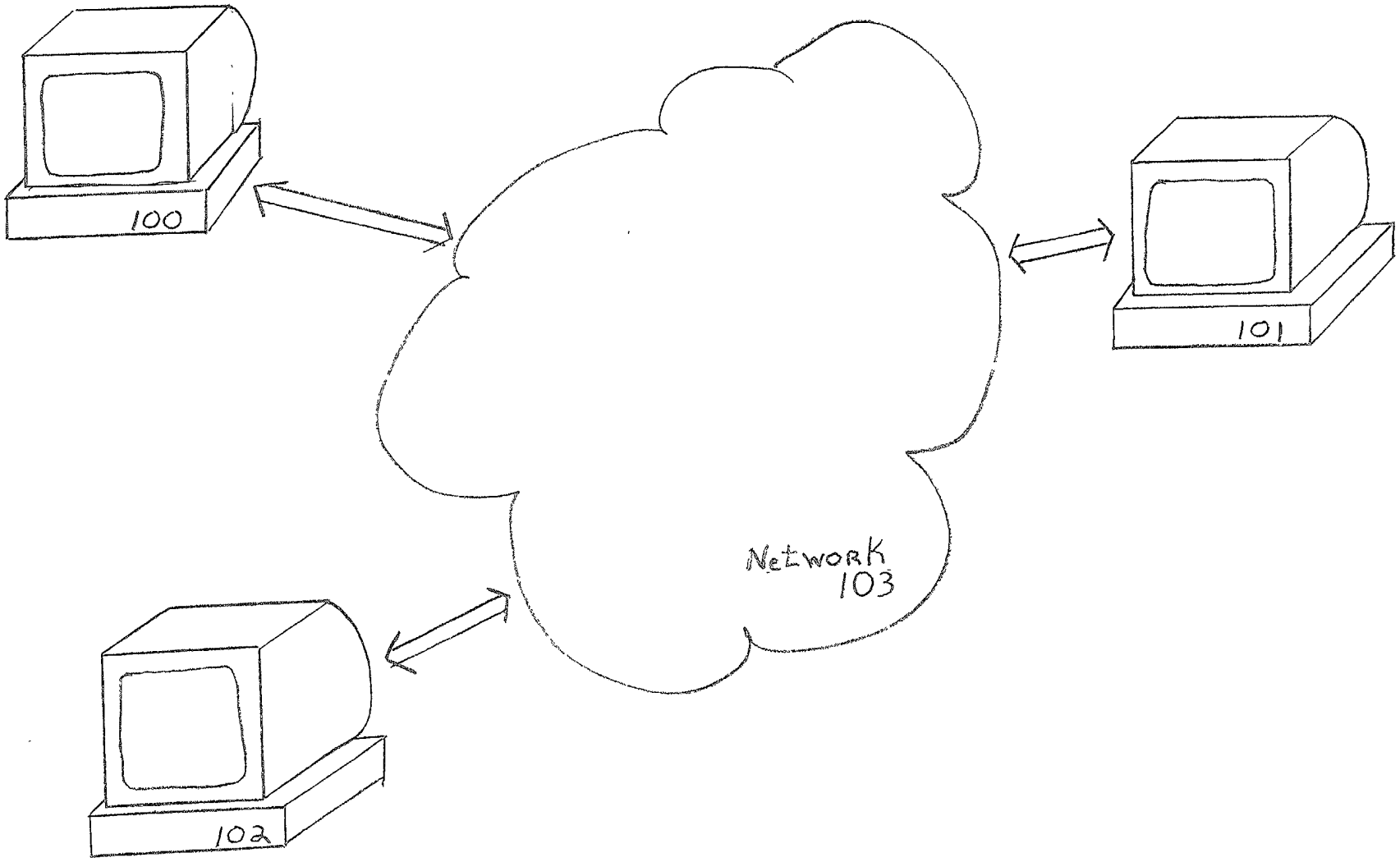
Fig. 1A



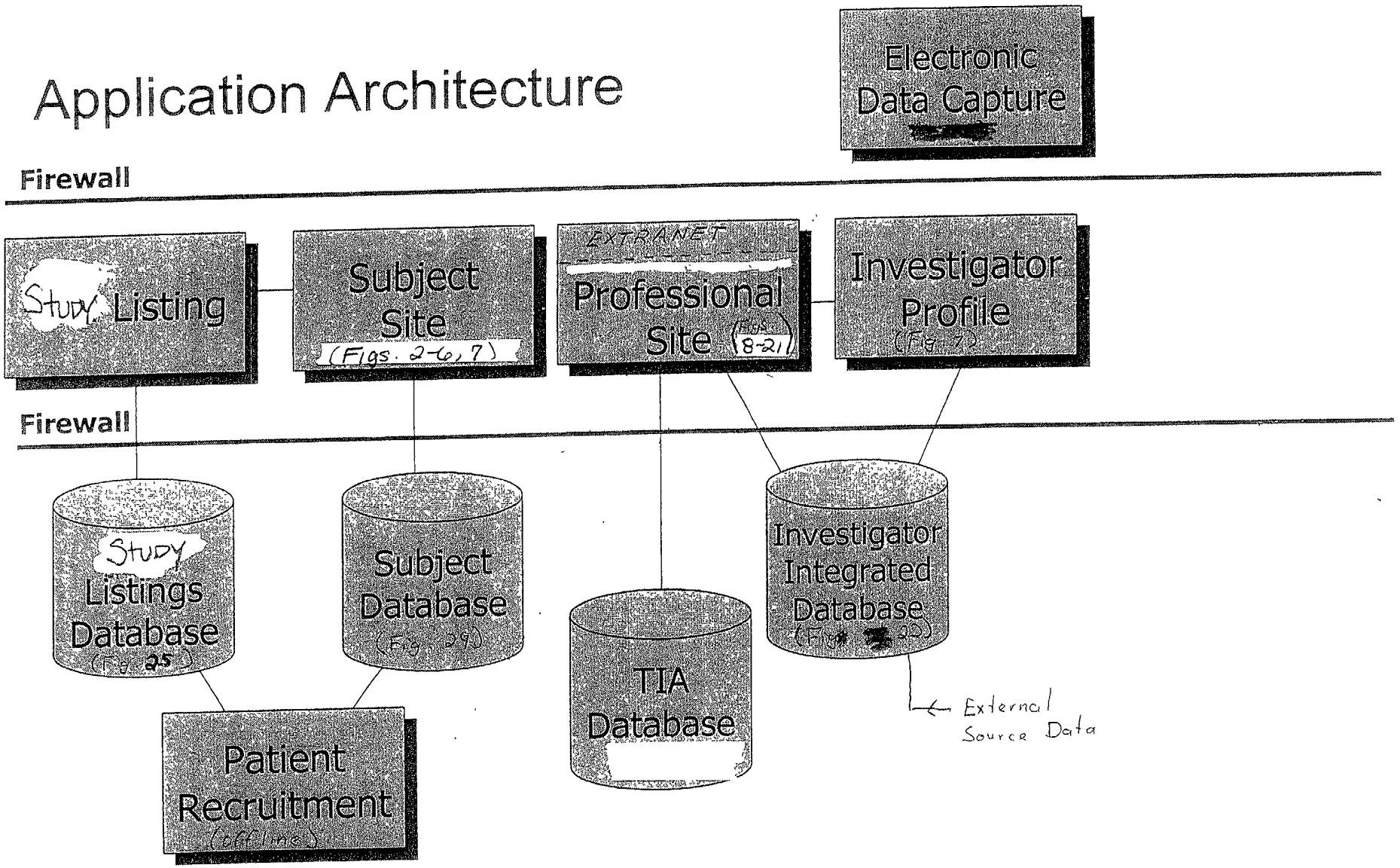
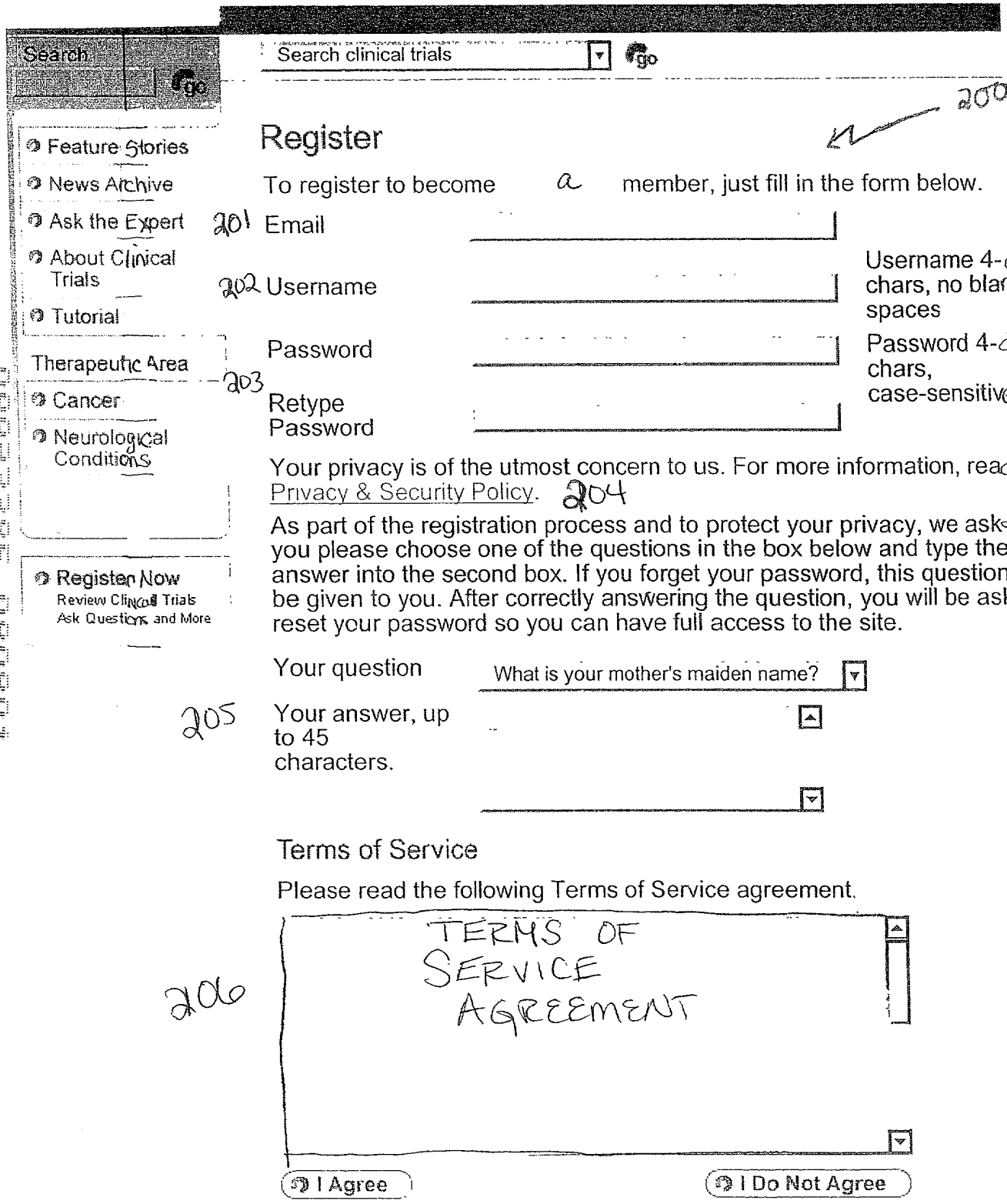

Application Architecture
Electronic Data Capture
Firewall
Study Listing
Subject Site
(Figs. 2-6, 7)
EXTRANET
Professional Site (Figs. 8-21)
Investigator Profile
(Fig. 22)
Firewall
Study Listings Database
(Fig. 25)
Subject Database
(Fig. 29)
TIA Database
Investigator Integrated Database
(Fig. 35)
Patient Recruitment
(offline)
External Source Data

Fig. 1B


Search
go
Search clinical trials
go
200
Feature Stories
News Archive
Ask the Expert
About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
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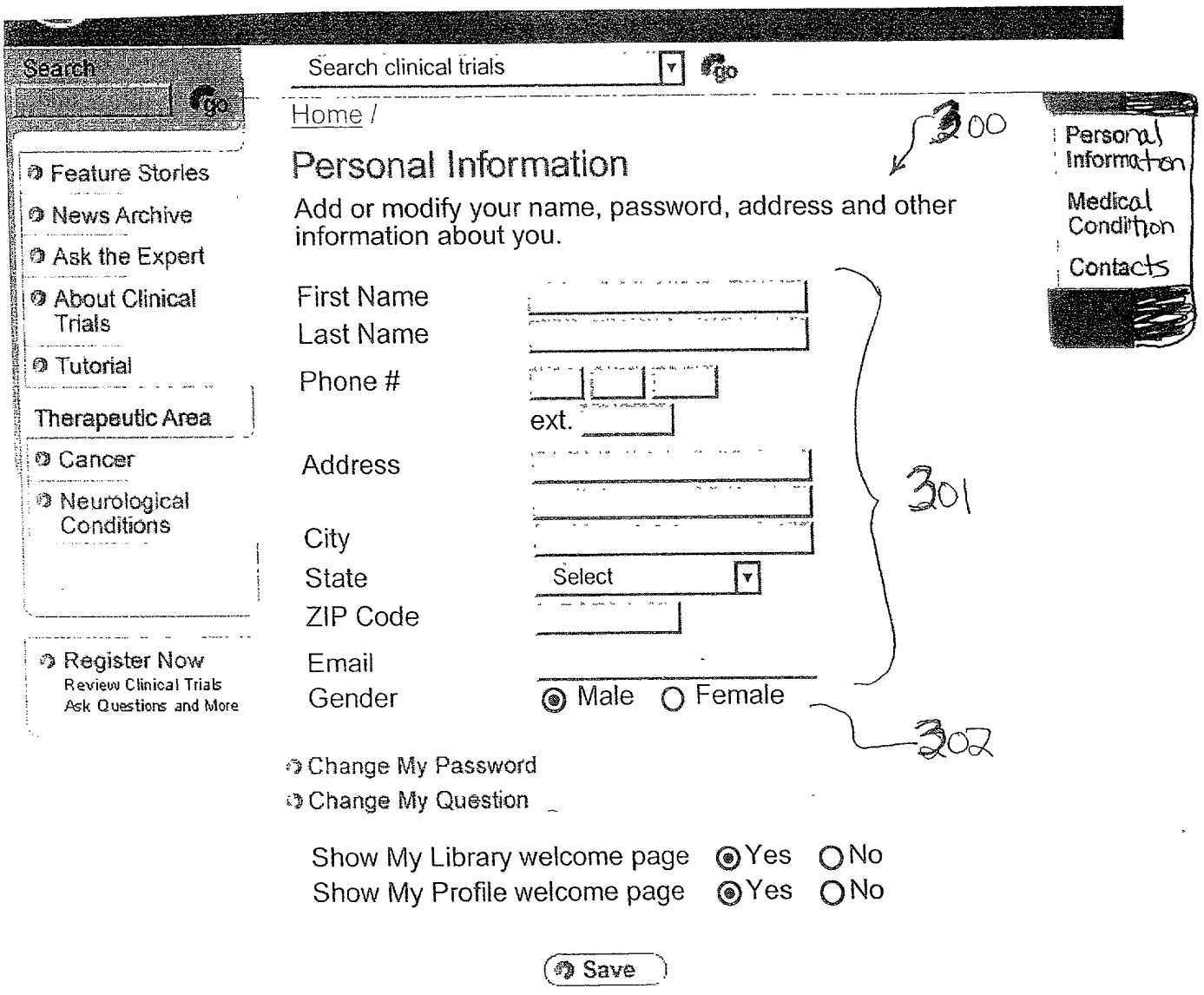
Register
To register to become a member, just fill in the form below.
201
Email
202
Username
Username 4-digits chars, no blank spaces
Password
Password 4-digits chars, case-sensitive
203
Retype Password
Your privacy is of the utmost concern to us. For more information, read Privacy & Security Policy.
204
As part of the registration process and to protect your privacy, we ask that you please choose one of the questions in the box below and type the answer into the second box. If you forget your password, this question will be given to you. After correctly answering the question, you will be asked to reset your password so you can have full access to the site.
Your question
What is your mother's maiden name?
205
Your answer, up to 45 characters.
Terms of Service
Please read the following Terms of Service agreement.
206
TERMS OF SERVICE AGREEMENT
I Agree
I Do Not Agree
Benefits of Registration
Registered users will benefit from:

Fig. 2A

- OUR comprehensive clinical trial listings - get trial information and out how you can be considered for participation in clinical trials
- The ability to ask questions of OUR medical experts
- Timely, relevant announcements of new trials and drug information
- Exclusive interactive tools, including your own personal library of news information
- Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection.
- A personal profile used to optimize your experience.

FIG. 2B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Personal Information
Add or modify your name, password, address and other information about you.
Personal Information
Medical Condition
Contacts
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Therapeutic Area
Cancer
Neurological Conditions
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First Name
Last Name
Phone #
ext.
Address
City
State
Select
ZIP Code
Email
Gender
Male
Female
301
302
Change My Password
Change My Question
Show My Library welcome page
Yes
No
Show My Profile welcome page
Yes
No
Save

Fig. 3

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Search clinical trials go

Search go

- Feature Stories
- News Archive
- Ask the Expert
- About Clinical Trials
- Tutorial

Therapeutic Area

- Cancer
- Neurological Conditions

- Register Now
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  Ask Questions and More

Home /

Medical Conditions

400

Select conditions that interest you and indicate the kind of information you would like to receive. Please select a therapeutic area in the pulldown menu and then click "View" to see the conditions that fall within that area.

If you'd like to see another therapeutic area, simply go to the pulldown menu, make another selection and then click "View." The page will automatically display the new therapeutic area.

401 402

Cancer View

Personal Information
Medical Condition
Contact

Cancer

Please email me updated information on:

Condition	404 Medical News/Drugs	405 Clinical Trial Opportunities
Abdominal Cancer	☐	☐
Acute T-Cell Lymphoma	☐	☐
Adrenal Cancer	☐	☐
Bladder Cancer	☐	☐
Bone Marrow Transplant	☐	☐
Bone Metastases	☐	☐
Brain Cancer	☐	☐
Breast Cancer	☐	☐
Cancer Pain	☐	☐
Cancer/Tumors	☐	☐
Cervical Cancer	☐	☐
Cervical Neoplasia	☐	☐
Chemotherapy	☐	☐
Colon Malignancies	☐	☐
Colon Polyps	☐	☐
Colorectal Cancer	☐	☐
Effects of Chemotherapy	☐	☐
Endometrial Cancer	☐	☐

403

FIG. 4A

Esophageal Cancer	☐	☐
Fibrocystic Breast	☐	☐
Gall Bladder Cancer	☐	☐
Gastric Cancer	☐	☐
Gliomas	☐	☐
Head and Neck Cancer	☐	☐
Hepatoblastoma	☐	☐
Histiocytoma	☐	☐
Islet Cell Cancer	☐	☐
Kaposi's Sarcoma	☐	☐
Kidney Cancer	☐	☐
Leukemia	☐	☐
Liver Cancer	☐	☐
Lung Cancer	☐	☐
Lymphomas	☐	☐
Malignant Adenoma	☐	☐
Malignant Melanoma	☐	☐
Medical Prosthetics	☐	☐
Meningiomas	☐	☐
Mesothelioma	☐	☐
Metastatic Cancer	☐	☐
Multiple Myelomas	☐	☐
Mycosis Fungoides	☐	☐
Neoplasms	☐	☐
Neurectoderma	☐	☐
Neuroblastoma	☐	☐
Neurofibromatosis	☐	☐
Non-Hodgkin's Lymphoma	☐	☐
Oral Cavity Cancer	☐	☐
Ovarian Cancer	☐	☐
Pancreatic Cancer	☐	☐
Pelvic Cancer	☐	☐
Platelet Deficiencies	☐	☐
Prostate Cancer	☐	☐
Rectal Cancer	☐	☐
Renal Cell Carcinoma	☐	☐
Sarcoma	☐	☐
Skin Cancer	☐	☐

Fig. 4B

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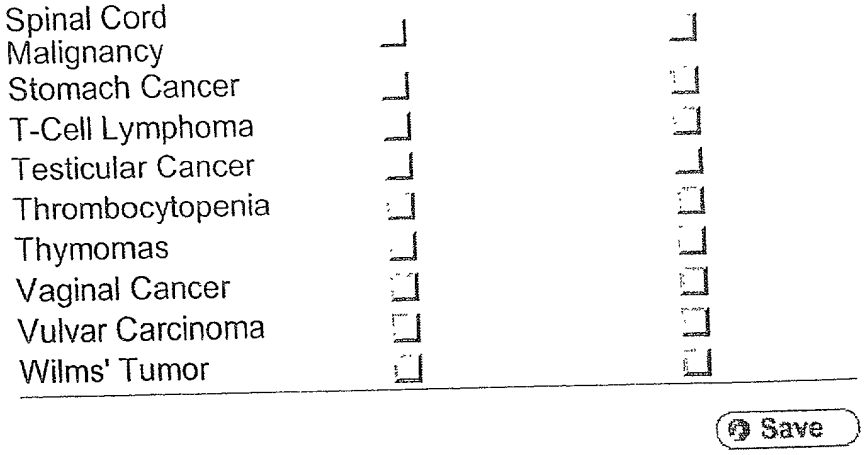
Spinal Cord Malignancy
Stomach Cancer
T-Cell Lymphoma
Testicular Cancer
Thrombocytopenia
Thymomas
Vaginal Cancer
Vulvar Carcinoma
Wilms' Tumor
Save

FIG. 4C

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Clinical

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Search clinical trials Go

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- Neurological Conditions

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About Clinical Trials

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- Cancer
- Cardiology/Vascular Diseases
- Dental/Maxillofacial Surgery
- Dermatology Plastic Surgery
- Endocrinology
- Gastroenterology
- Hematology
- Immunology/Infectious Diseases
- Musculoskeletal
- Nephrology/Urology
- Neurological Conditions
- Obstetrics/Gynecology
- Ophthalmology
- Otolaryngology
- Pediatrics/Neonatology
- Pharmacology/Toxicology
- Pulmonary/Respiratory Diseases
- Rheumatology
- Trauma/Emergency Medicine

501

Clinical Trials FAQ

- Introduction: What are clinical trials?
- Why are clinical trials important?
- The clinical trial process.
- How are participant's rights and safety protected during a clinical trial?
- Who pays for clinical trials?
- Where can you get more information about clinical trials?
- Questions you need to ask.
- Common terms used in clinical trials.

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Introduction: What are clinical trials?

Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the

Fig. 5A

drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

Back to top

Why are clinical trials important?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

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The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

Phase II. In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

FIG. 5B

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Phase III. In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

Phase IV. Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

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How are participant's rights and safety protected during a clinical trial?

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

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Who pays for clinical trials?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.
- Sponsors may pay you to participate in a clinical trial. Typically, these fees, when provided, are nominal.
- Medical care is often provided at no cost to the

FIG 5C

patients, but they still may be responsible for other expenses such as travel between their homes and the healthcare facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

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Where can you get more information about clinical trials?

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your healthcare provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

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Questions you need to ask.

- What is the length of your involvement in the clinical trial? How long will the trial last?
- Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- Do the treatment alternatives they provide cover all possible treatments for this disease? If not, what are your other treatment alternatives?
- What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study?
- What costs may you incur if you participate?
- Will the treatment be available to you even after the clinical trial has concluded?
- Where are the funds coming from to conduct this trial? What is their purpose in sponsoring the trial?

You should also feel free to ask any other question about the trial you want answered.

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Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and

FIG 5D

benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

Informed consent: Informed consent is a process that confirms a patient understands the nature of the study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

Principal investigator: The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

Protocol: A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

Sponsor: The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

FIG. 5E

Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the 'best treatment' currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

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FIG. 5F

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Clinical

Search clinical trials go

Search go

- Feature Stories
- News Archive
- Ask the Expert
- About Clinical Trials
- Tutorial

Therapeutic Area

- Cancer
- Neurological Conditions

- Register Now
  Review Clinical Trials
  Ask Questions and More

Home / Cancer /

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Clinical Trials

Search Clinical Trials

Use these search criteria to find clinical trials.

Select a condition 602

601

and/or

Select a state go 603

Contact me for a clinical trial 604

Welcome to Clinical Trials

When a promising new medication is identified, careful evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration — the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on

FIG. 6A

clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

FIG. 6B

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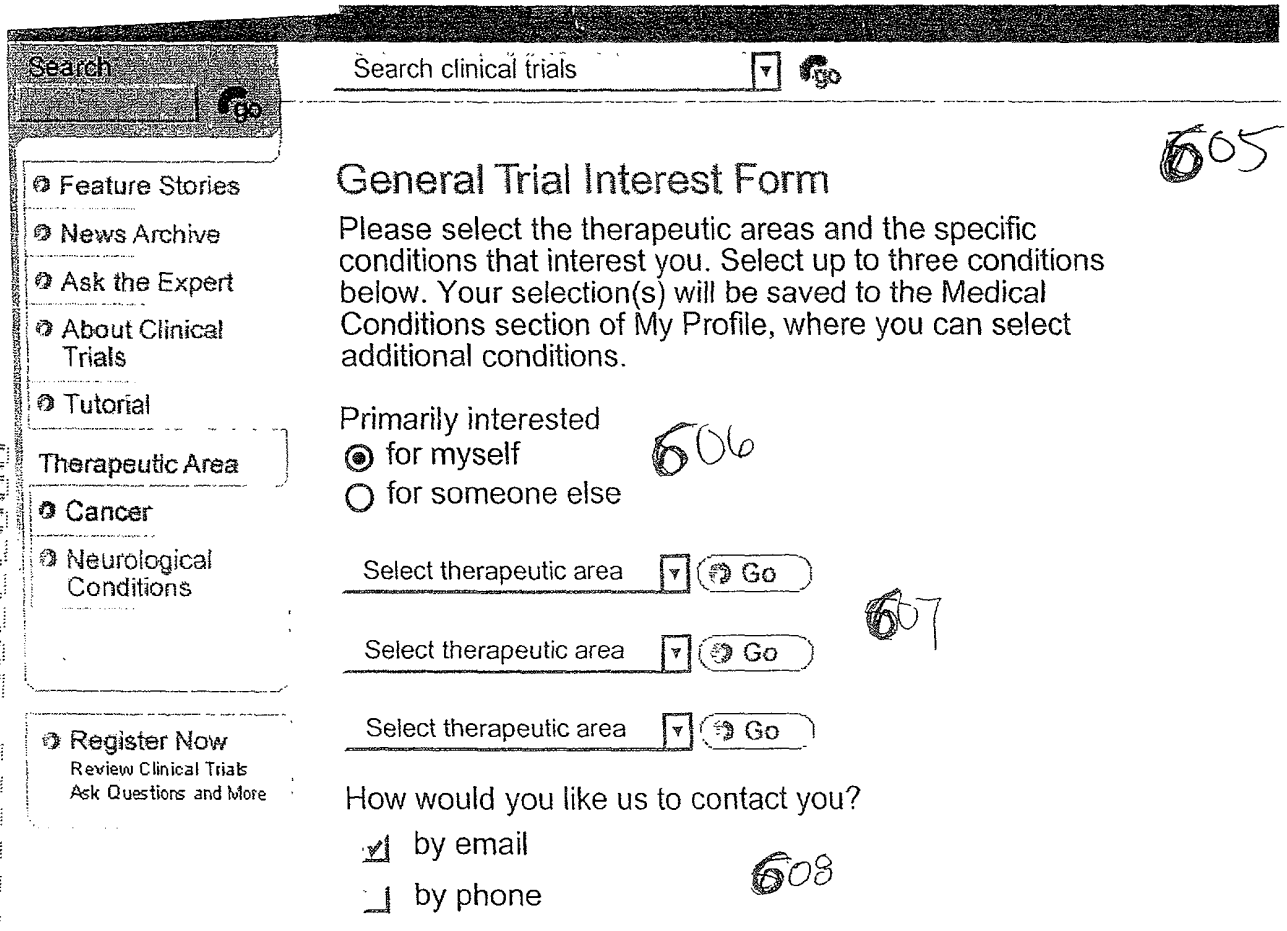
Search
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Therapeutic Area
Cancer
Neurological Conditions
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Ask Questions and More
General Trial Interest Form
Please select the therapeutic areas and the specific conditions that interest you. Select up to three conditions below. Your selection(s) will be saved to the Medical Conditions section of My Profile, where you can select additional conditions.
Primarily interested
for myself
for someone else
Select therapeutic area
Go
Select therapeutic area
Go
Select therapeutic area
Go
How would you like us to contact you?
by email
by phone
by regular mail
First Name
Last Name
Phone #
ext.
Email
Address
City
State
Select state
ZIP Code
Best time to contact you
day
Willing to travel
1-10 miles
Submit
Cancel
605
606
607
608
609
610
611

FIG. 6C

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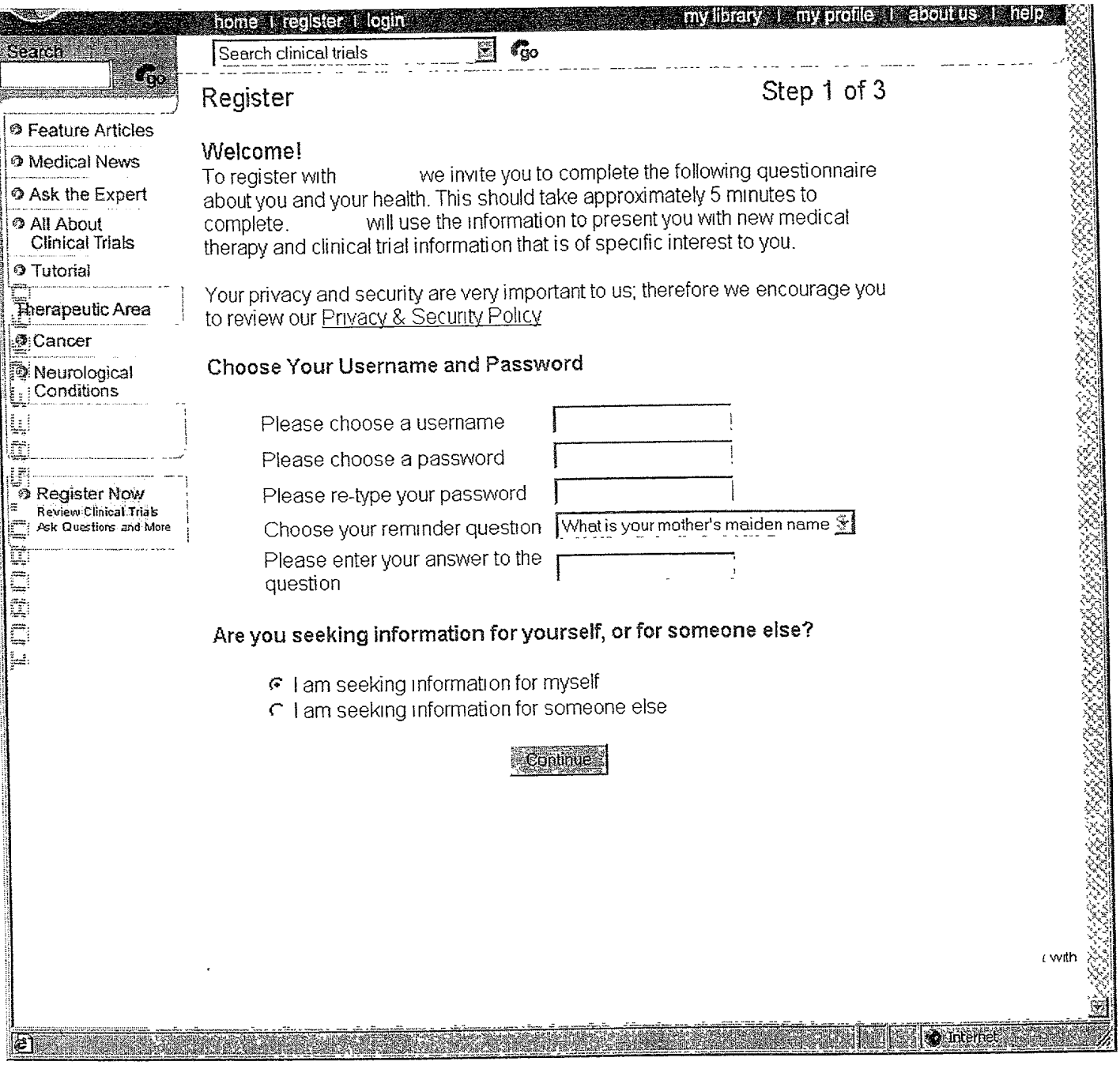
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Search
Search clinical trials
Go
Register
Step 1 of 3
Feature Articles
Medical News
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Therapeutic Area
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Register Now
Review Clinical Trials
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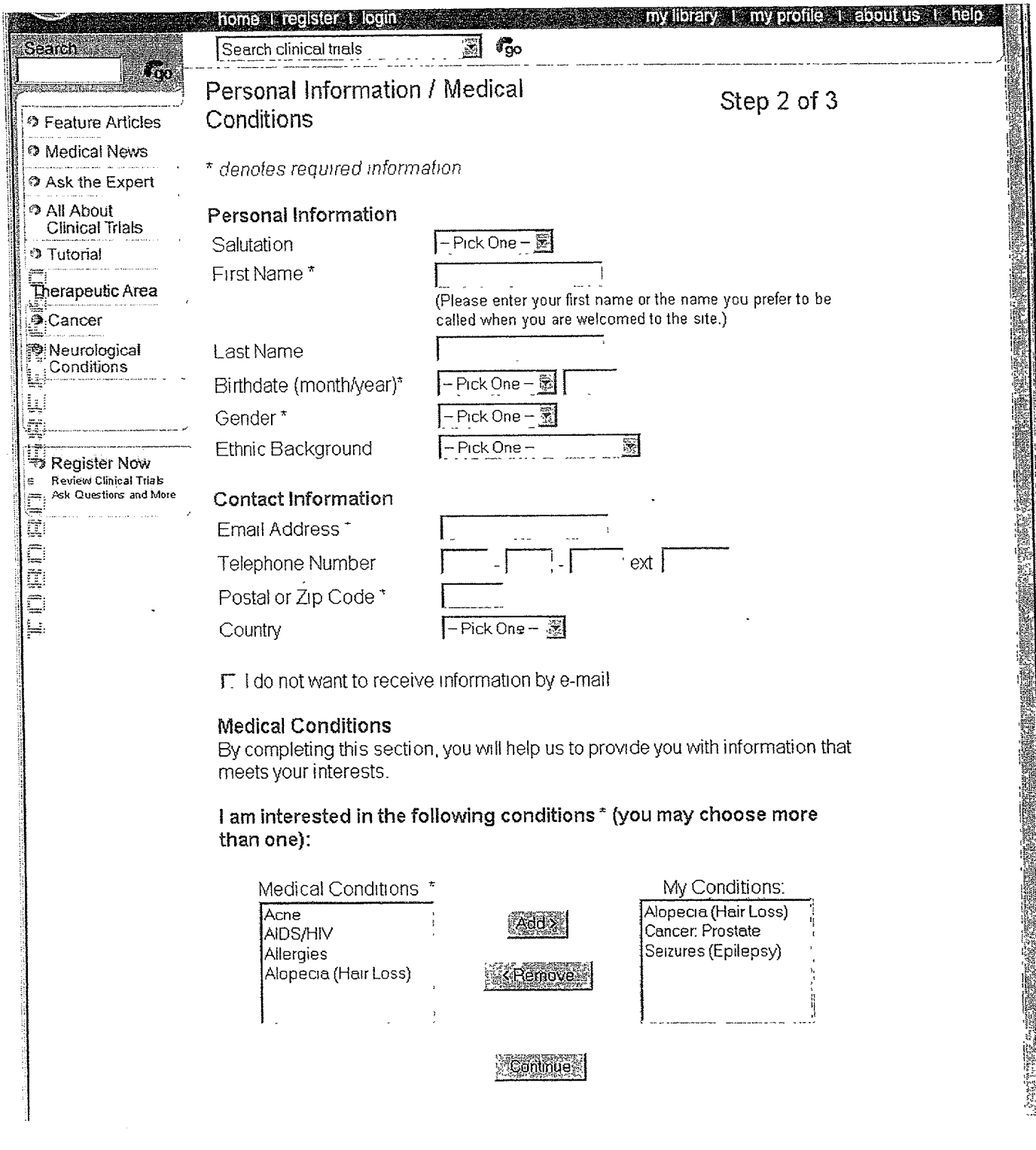
Welcome!
To register with we invite you to complete the following questionnaire about you and your health. This should take approximately 5 minutes to complete. will use the information to present you with new medical therapy and clinical trial information that is of specific interest to you.
Your privacy and security are very important to us; therefore we encourage you to review our Privacy & Security Policy
Choose Your Username and Password
Please choose a username
Please choose a password
Please re-type your password
Choose your reminder question
What is your mother's maiden name
Please enter your answer to the question
Are you seeking information for yourself, or for someone else?
I am seeking information for myself
I am seeking information for someone else
Continue
with
Internet

Fig 6D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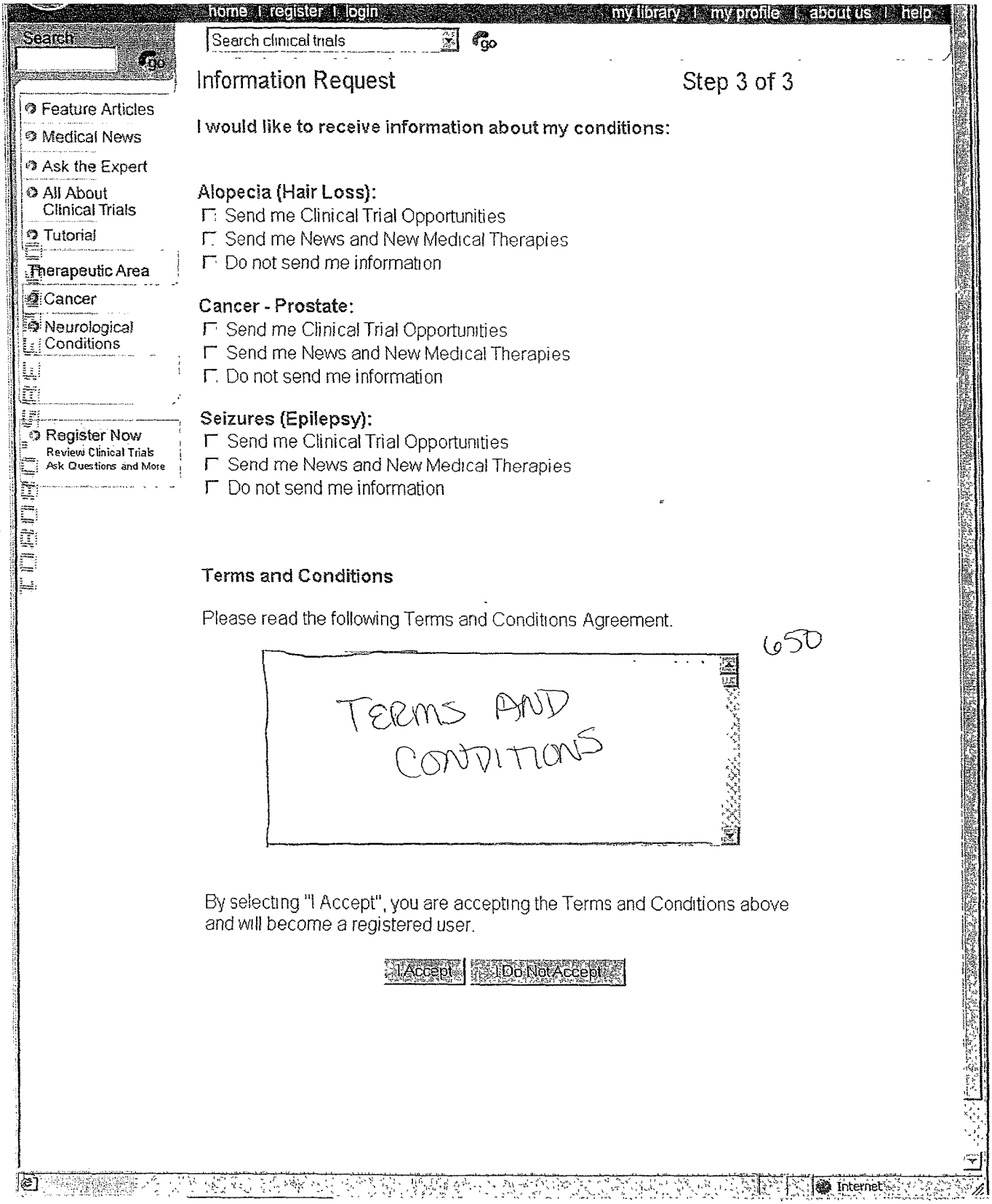
Personal Information / Medical Conditions
Step 2 of 3
* denotes required information
Personal Information
Salutation
– Pick One –
First Name *
(Please enter your first name or the name you prefer to be called when you are welcomed to the site.)
Last Name
Birthdate (month/year)*
– Pick One –
Gender *
– Pick One –
Ethnic Background
– Pick One –
Contact Information
Email Address *
Telephone Number
ext
Postal or Zip Code *
Country
– Pick One –
I do not want to receive information by e-mail
Medical Conditions
By completing this section, you will help us to provide you with information that meets your interests.
I am interested in the following conditions * (you may choose more than one):
Medical Conditions *
Acne
AIDS/HIV
Allergies
Alopecia (Hair Loss)
Add >
< Remove
My Conditions:
Alopecia (Hair Loss)
Cancer: Prostate
Seizures (Epilepsy)
Continue

Fig. 6E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Ask Questions and More
Information Request
Step 3 of 3
I would like to receive information about my conditions:
Alopecia (Hair Loss):
Send me Clinical Trial Opportunities
Send me News and New Medical Therapies
Do not send me information
Cancer - Prostate:
Send me Clinical Trial Opportunities
Send me News and New Medical Therapies
Do not send me information
Seizures (Epilepsy):
Send me Clinical Trial Opportunities
Send me News and New Medical Therapies
Do not send me information
Terms and Conditions
Please read the following Terms and Conditions Agreement.
650
TERMS AND CONDITIONS
By selecting "I Accept", you are accepting the Terms and Conditions above and will become a registered user.
I Accept
I Do Not Accept
Internet

Fig. 6F

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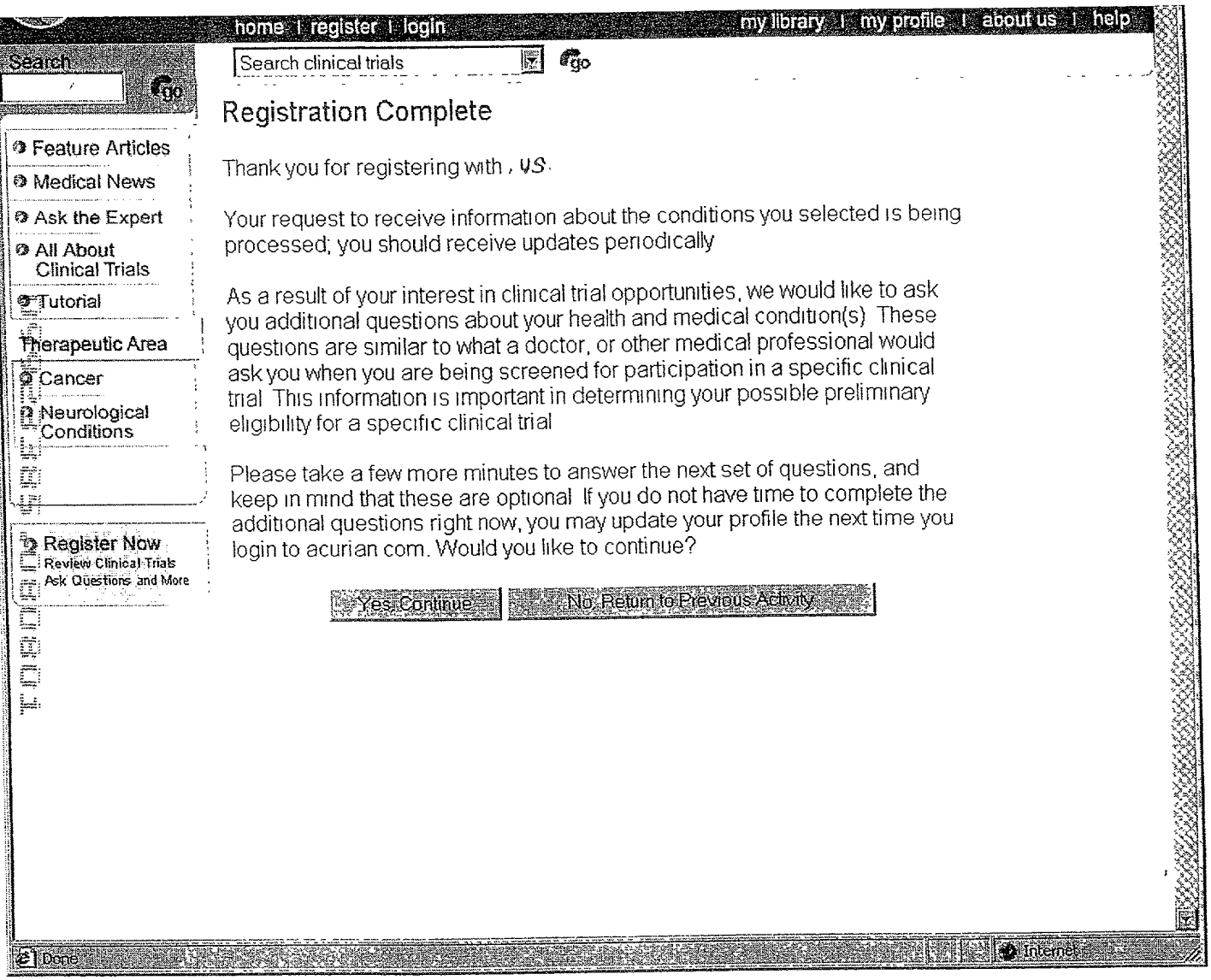
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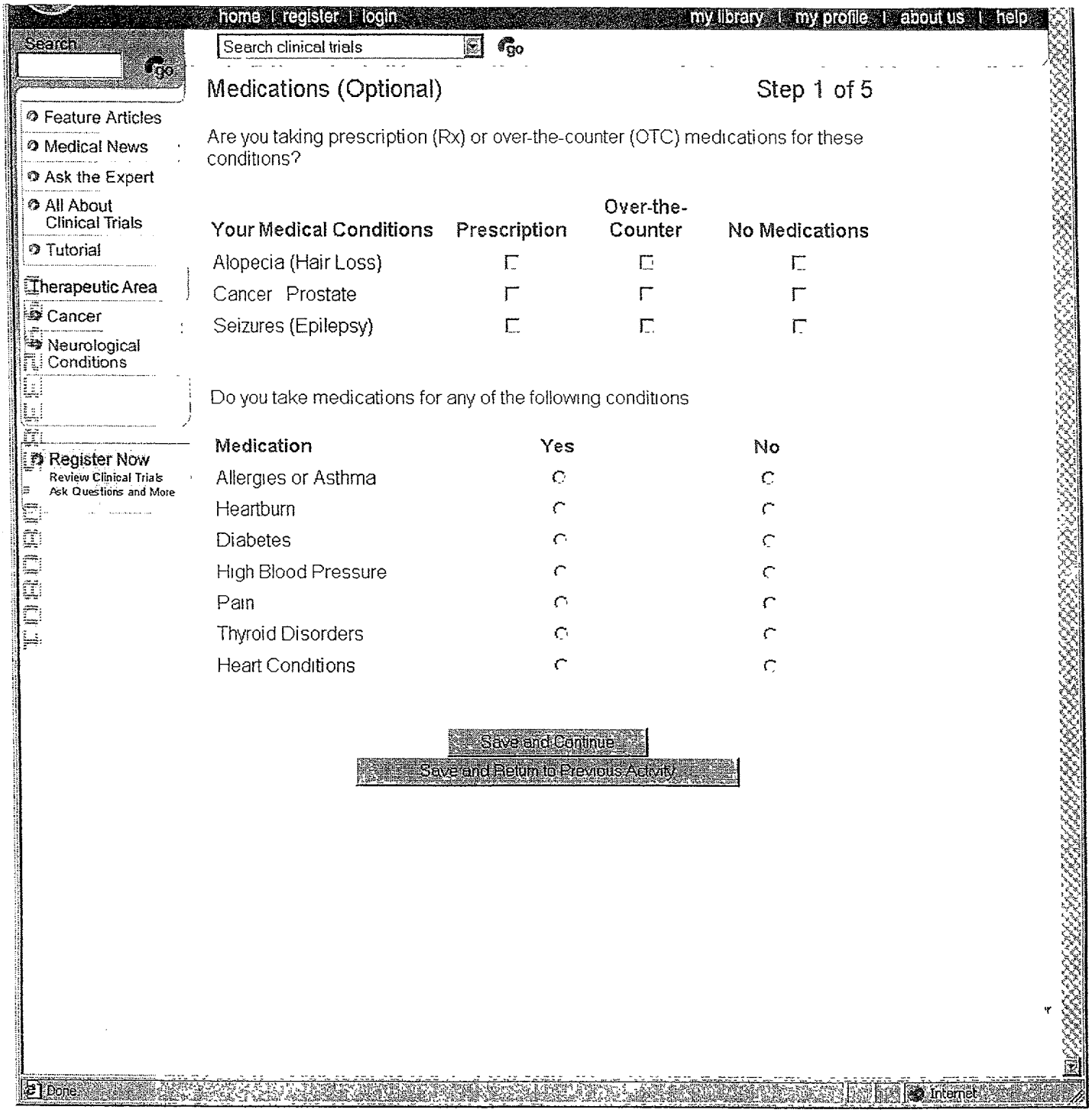
Search clinical trials
go
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More
Registration Complete
Thank you for registering with , US.
Your request to receive information about the conditions you selected is being processed; you should receive updates periodically
As a result of your interest in clinical trial opportunities, we would like to ask you additional questions about your health and medical condition(s) These questions are similar to what a doctor, or other medical professional would ask you when you are being screened for participation in a specific clinical trial This information is important in determining your possible preliminary eligibility for a specific clinical trial
Please take a few more minutes to answer the next set of questions, and keep in mind that these are optional If you do not have time to complete the additional questions right now, you may update your profile the next time you login to acurian com. Would you like to continue?
Yes, Continue
No, Return to Previous Activity
Done
Internet

Fig. 6G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Search clinical trials
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Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
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Ask Questions and More
Medications (Optional)
Step 1 of 5
Are you taking prescription (Rx) or over-the-counter (OTC) medications for these conditions?
Your Medical Conditions
Prescription
Over-the-Counter
No Medications
Alopecia (Hair Loss)
Cancer Prostate
Seizures (Epilepsy)
Do you take medications for any of the following conditions
Medication
Yes
No
Allergies or Asthma
Heartburn
Diabetes
High Blood Pressure
Pain
Thyroid Disorders
Heart Conditions
Save and Continue
Save and Return to Previous Activity
Done
Internet

Fig. 6H

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Therapeutic Area
Cancer
Neurological Conditions
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Health Habits (Optional) Step 2 of 5

It is often important to know your health habits when presenting you with possible clinical trial opportunities

How often do you exercise?
- ○ Never
- ○ Once a week
- ○ Twice a week
- ○ Three times a week
- ○ Four or more times a week
- ○ Daily

How often do you visit your primary care physician?
- ○ Once a year
- ○ 2-4 times a year
- ○ Every month
- ○ I do not have a primary care physician

Do you smoke cigarettes?
- ○ No, I have never smoked
- ○ No, I quit smoking
- ○ Yes, daily
- ○ Yes, occasionally

If you smoke, how many cigarettes do you smoke per day?
Please enter [ ] Cigarettes Per Day

If you smoke, how old were you when you started smoking?
Please enter [ ] years old

Do you drink alcoholic beverages?
- ○ No
- ○ Yes, occasionally
- ○ Yes, 1-2 drinks per day
- ○ Yes, more than 2 drinks per day

Overall, how would you rate your health?
- ○ Excellent
- ○ Good
- ○ Fair
- ○ Poor

Save and Continue
Save and Return to Previous Activity

Fig. 6I

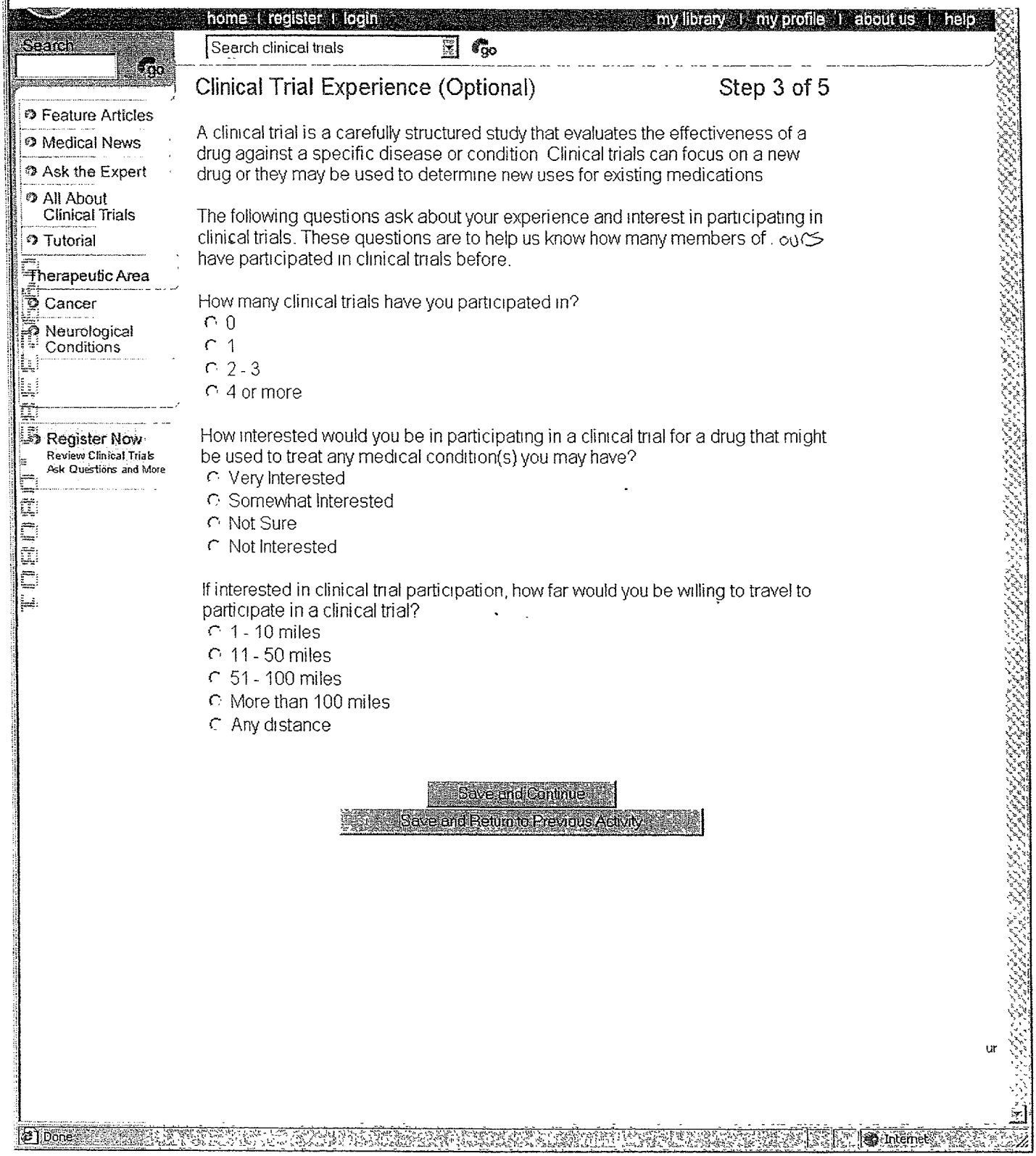

home | register | login
my library | my profile | about us | help
Search
Search clinical trials
go
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More
Clinical Trial Experience (Optional)
Step 3 of 5
A clinical trial is a carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications
The following questions ask about your experience and interest in participating in clinical trials. These questions are to help us know how many members of . ours have participated in clinical trials before.
How many clinical trials have you participated in?
0
1
2 - 3
4 or more
How interested would you be in participating in a clinical trial for a drug that might be used to treat any medical condition(s) you may have?
Very Interested
Somewhat Interested
Not Sure
Not Interested
If interested in clinical trial participation, how far would you be willing to travel to participate in a clinical trial?
1 - 10 miles
11 - 50 miles
51 - 100 miles
More than 100 miles
Any distance
Save and Continue
Save and Return to Previous Activity
ur
Done
Internet

Fig. 6J

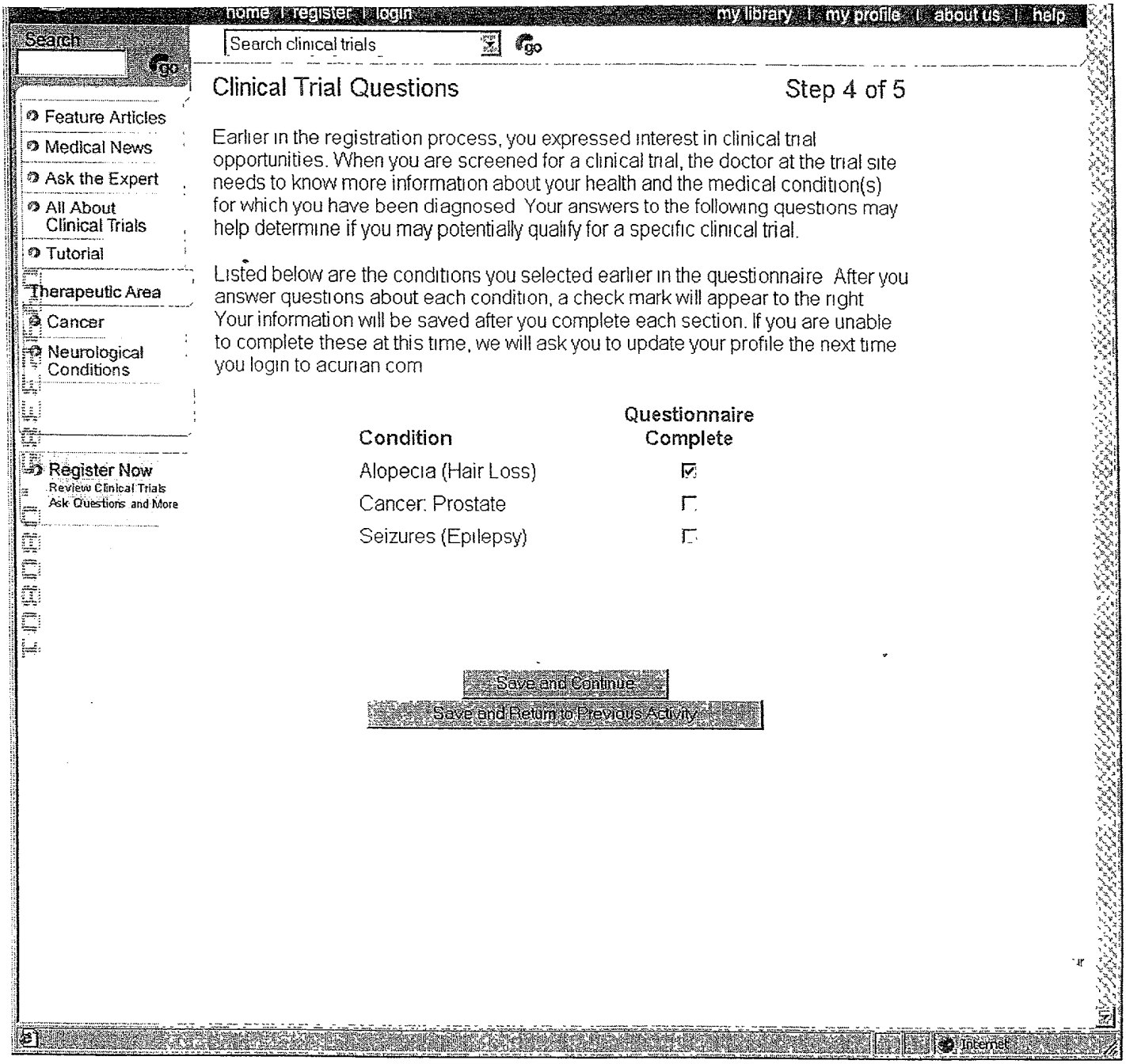

home | register | login
my library | my profile | about us | help
Search
go
Search clinical trials
go
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More
Clinical Trial Questions
Step 4 of 5
Earlier in the registration process, you expressed interest in clinical trial opportunities. When you are screened for a clinical trial, the doctor at the trial site needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.
Listed below are the conditions you selected earlier in the questionnaire. After you answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com
Condition
Questionnaire Complete
Alopecia (Hair Loss)
Cancer: Prostate
Seizures (Epilepsy)
Save and Continue
Save and Return to Previous Activity
Internet

Fig. 6K

26/69

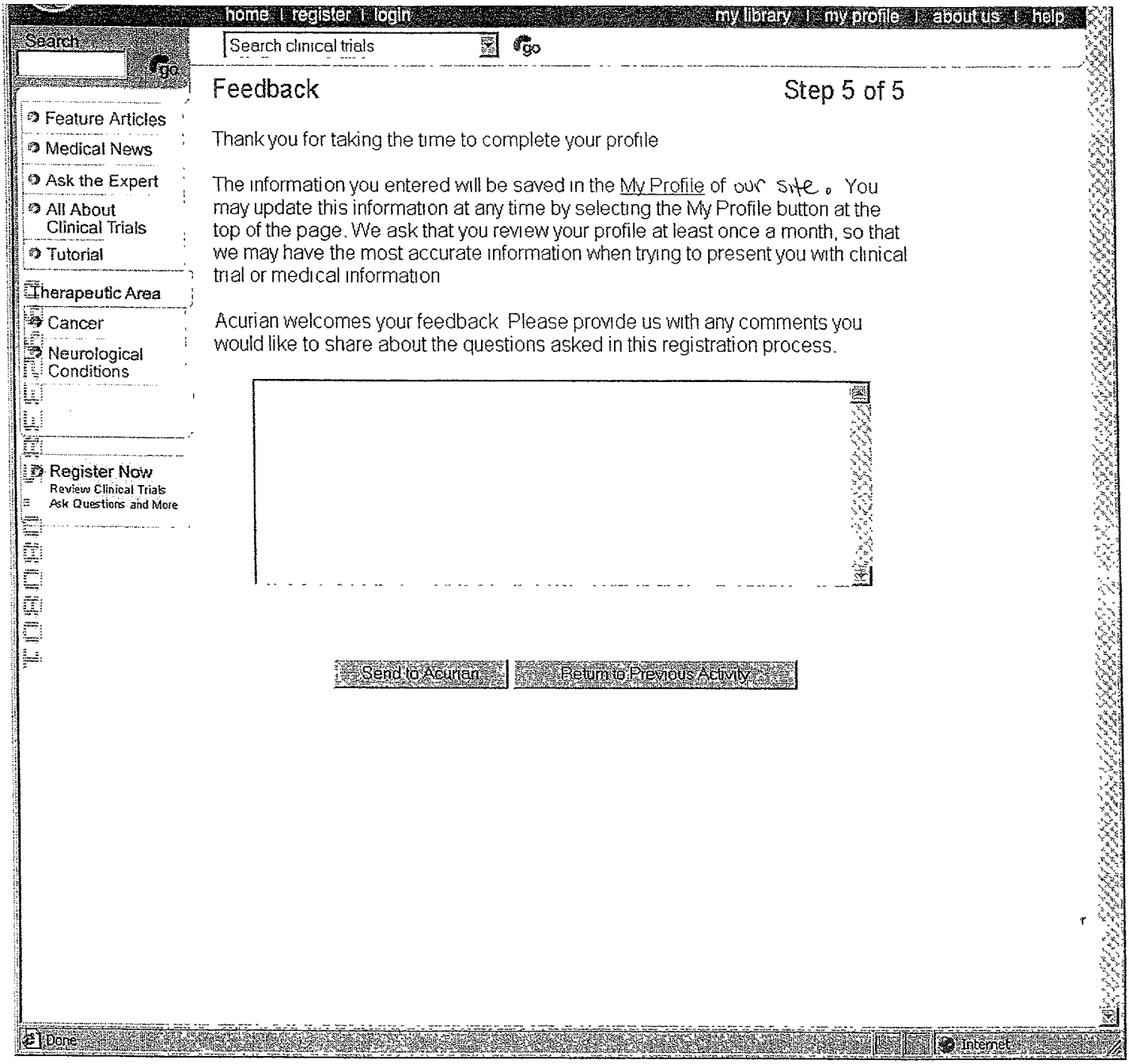

home | register | login
my library | my profile | about us | help
Search
go
Search clinical trials
go
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More
Feedback
Step 5 of 5
Thank you for taking the time to complete your profile
The information you entered will be saved in the My Profile of our site. You may update this information at any time by selecting the My Profile button at the top of the page. We ask that you review your profile at least once a month, so that we may have the most accurate information when trying to present you with clinical trial or medical information
Acurian welcomes your feedback Please provide us with any comments you would like to share about the questions asked in this registration process.
Send to Acurian
Return to Previous Activity
Done
Internet

Fig 6L

2/1/09

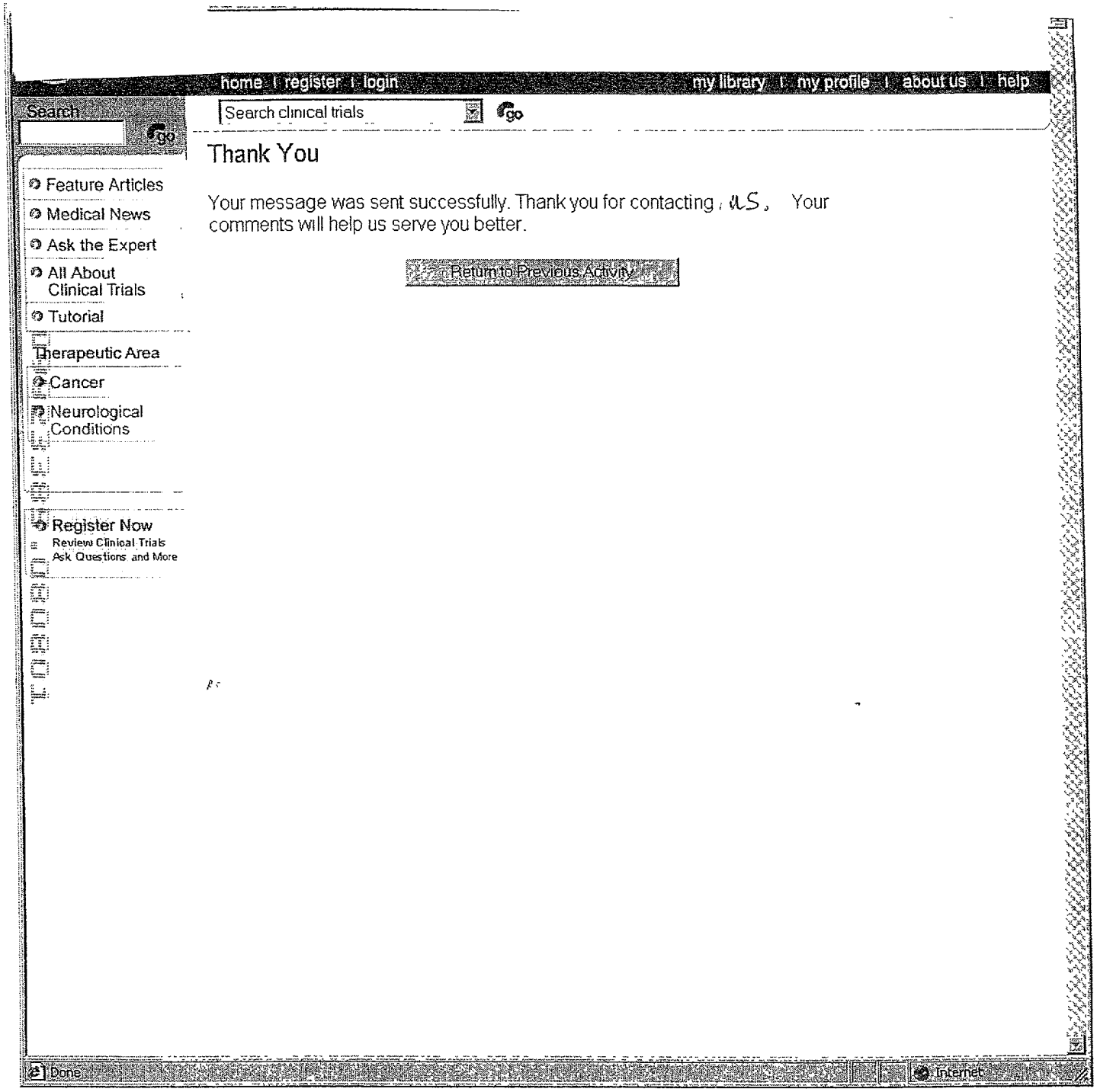

home | register | login
my library | my profile | about us | help
Search
go
Search clinical trials
go
Feature Articles
Medical News
Ask the Expert
All About Clinical Trials
Tutorial
Therapeutic Area
Cancer
Neurological Conditions
Register Now
Review Clinical Trials
Ask Questions and More
Thank You
Your message was sent successfully. Thank you for contacting us. Your comments will help us serve you better.
Return to Previous Activity
Done
Internet

Fig- 6M

2/8/09

Search clinical trials

Search

Home / Knowledge Center /

612

- Feature Stories
- News Archive
- Ask the Expert
- About Clinical Trials
- Tutorial

Therapeutic Area

- Cancer
- Neurological Conditions

- Register Now
  Review Clinical Trials
  Ask Questions and More

Welcome to My Library

Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information, perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.

In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.

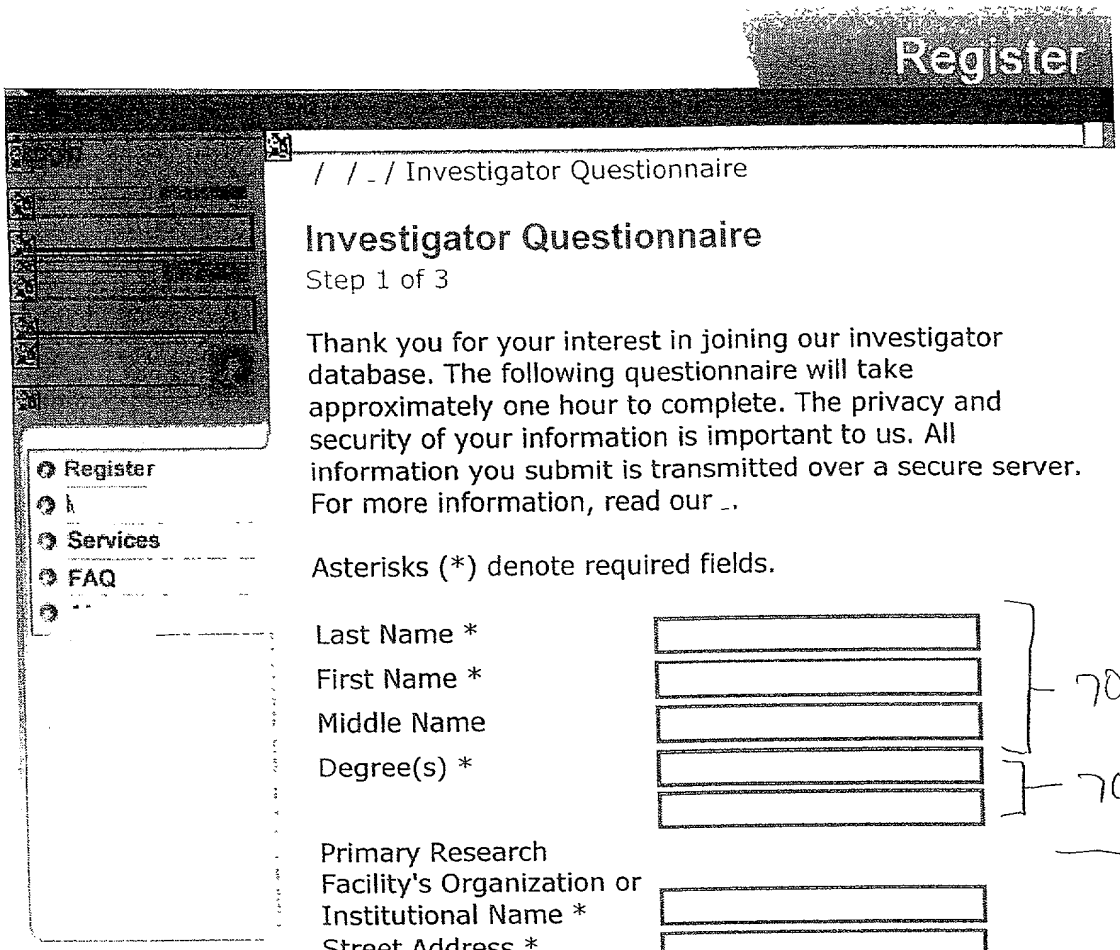
If you'd like to go directly to one of the five sections, select a link below:

- News
- Drug Information
- Clinical Trials
- Ask The Expert
- Feature Stories

☐ Do not show this page again.

FIG. 6N

29/89



Investigator Questionnaire

Step 1 of 3

700

Thank you for your interest in joining our investigator database. The following questionnaire will take approximately one hour to complete. The privacy and security of your information is important to us. All information you submit is transmitted over a secure server. For more information, read our _.

Asterisks (*) denote required fields.

Last Name *
First Name *
Middle Name
Degree(s) *

701

702

Primary Research Facility's Organization or Institutional Name *
Street Address *
City *
State / Province / Region *
Country *
Zip Code / Postal Code *
Phone (with area code) *
Telephone Extension
Fax (with area code)
Email Address

-- Select State/Province --
-- Select Country --

703

Primary Specialty *

-- Select One --

704

Board Certification(s) * ○ Yes ○ No
Year of Certification
Board Eligible * ○ Yes ○ No
Sub Specialty
Board Certification(s) ○ Yes ○ No
Year of Certification
Board Eligible ○ Yes ○ No

705

Number of years Investigator has participated in trials? *

706

FIG 7A

30/89

Indicate all phases of clinical research in which the Investigator participated *

☐ Phase I ☐ Phase II
☐ Phase III ☐ Phase IV

706

How many investigators conduct research at this PRF? *

☐ investigators

707

Is the Investigator affiliated with: *(check all that apply)*

☐ Local IRB ☐ Central IRB
☐ IEC (Canadian sites only)

If affiliated with a local IRB, what is its name?

How often does the local IRB meet?

☐ Weekly ☐ Bi-weekly
☐ Monthly ☐ As Needed
☐ Other

If "other", frequency of local IRB meeting?

How soon after the IRB meeting will you receive an approval letter?

708

Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency?

○ Yes ○ No

1. If yes, what was the date of the audit?

Who was the auditor?

If audited, was a 483 issued?

○ Yes ○ No

What were the results of the audit?

2. If yes, what was the date of the audit?

Who was the auditor?

If audited, was a 483 issued?

○ Yes ○ No

What were the results of the audit?

709

FIG. 7B

Has the Investigator gone through an audit by a sponsor or CRO? ○ Yes ○ No

1. If yes, what was the date of the audit? [ ]

Who was the auditor? [ ]

What were the results of the audit? [ ]

2. If yes, what was the date of the audit? [ ]

Who was the auditor? [ ]

What were the results of the audit? [ ]

710

Is your PRF
- ☐ Single specialty
- ☐ Multi-specialty

If PRF is multi-specialty, indicate specialties. (one per line) [ ] [ ] [ ]

Is your facility part of
- ☐ Solo practice
- ☐ Group practice

Is the facility affiliated with a Site Management Organization (SMO) or research group? ○ Yes ○ No

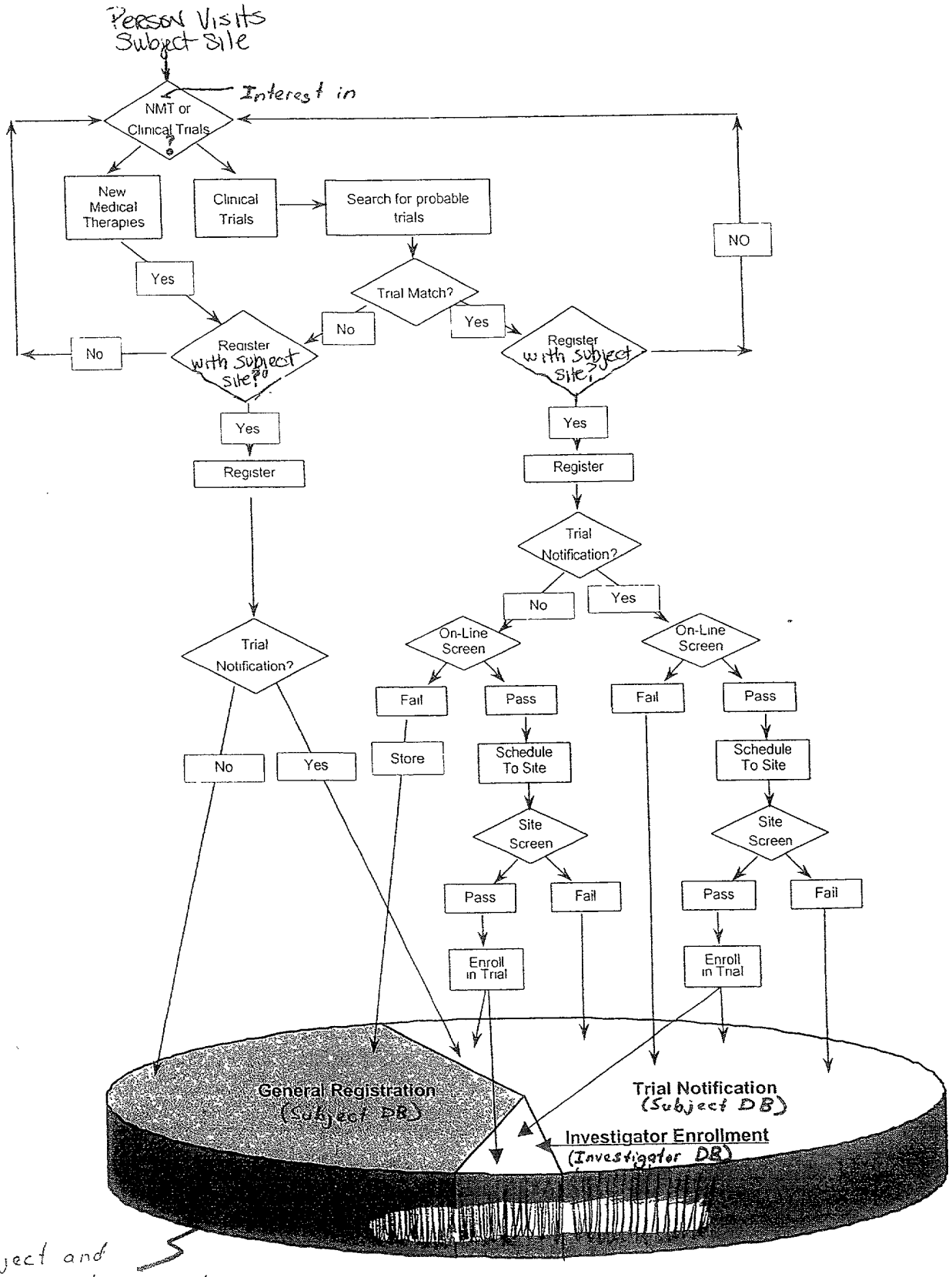
If affiliated, please specify the SMO name [ ]

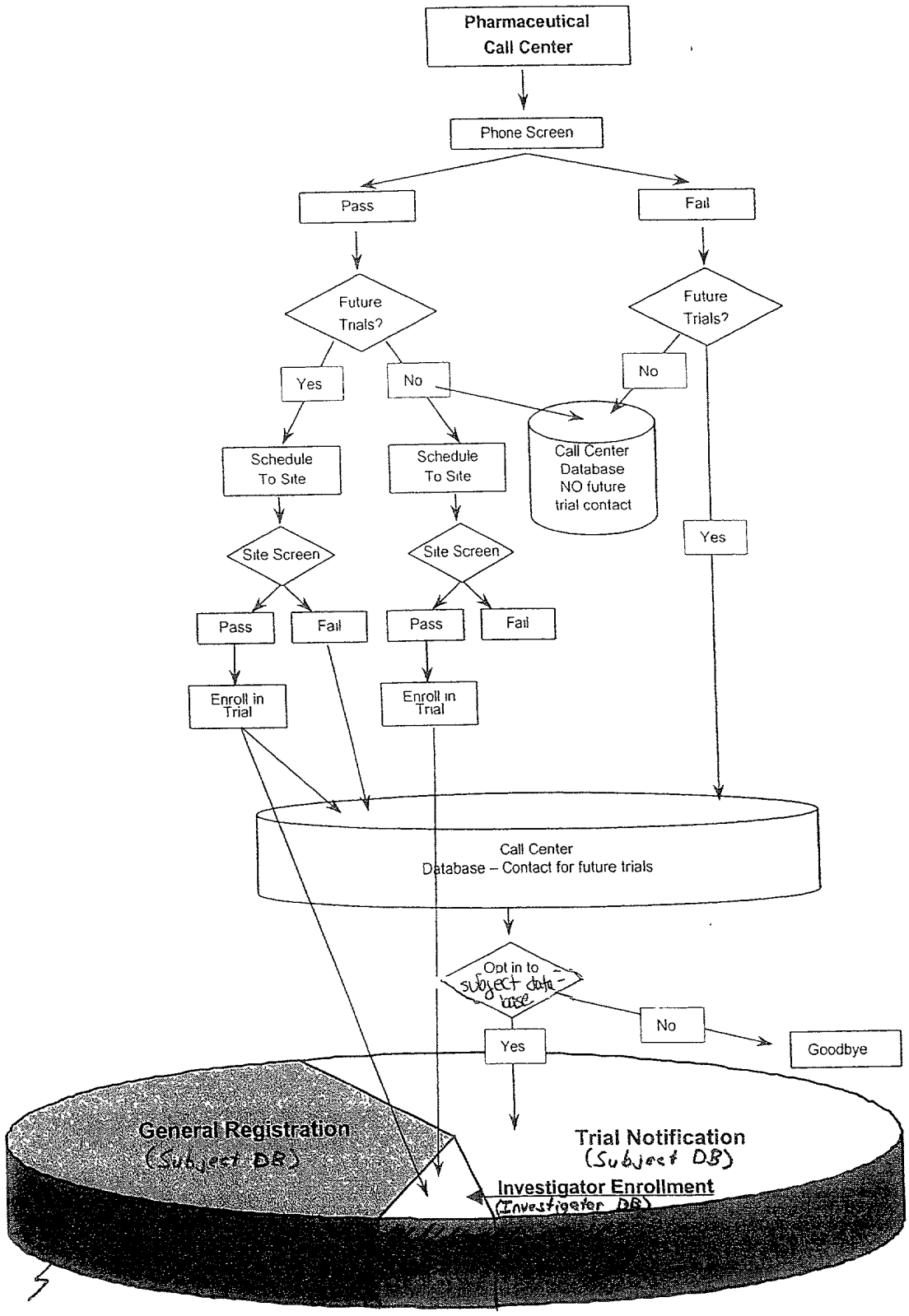
If affiliated, is this an exclusive relationship? ○ Yes ○ No

711

Cancel   Save and Continue

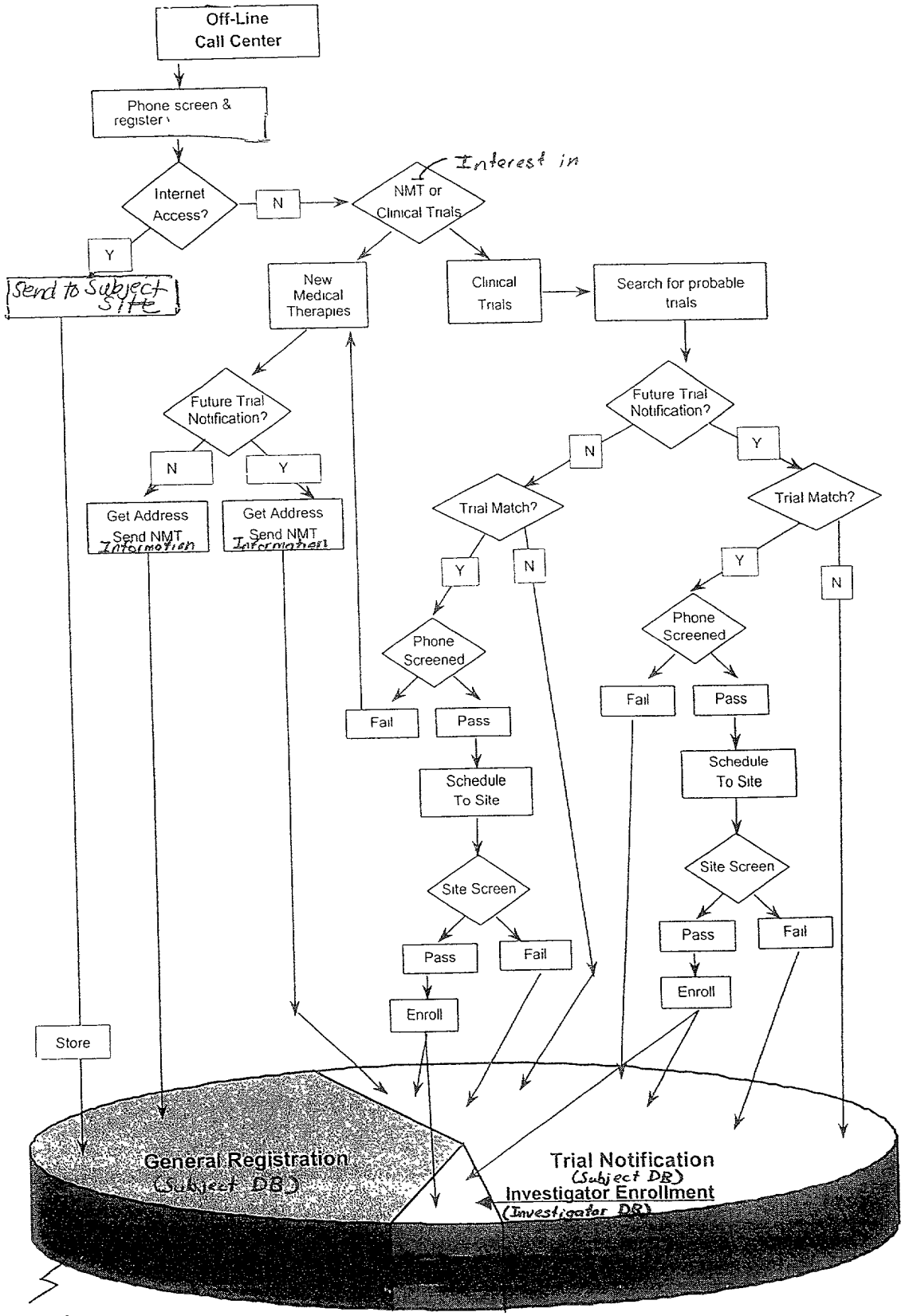
FIG. 7C


Person Visits Subject Site
Interest in
NMT or Clinical Trials?
New Medical Therapies
Clinical Trials
Search for probable trials
NO
Yes
Trial Match?
No
Yes
No
Register with Subject Site?
Register with Subject Site?
Yes
Yes
Register
Register
Trial Notification?
No
Yes
Trial Notification?
On-Line Screen
On-Line Screen
No
Yes
Fail
Pass
Fail
Pass
Store
Schedule To Site
Schedule To Site
Site Screen
Site Screen
Pass
Fail
Pass
Fail
Enroll in Trial
Enroll in Trial
General Registration (Subject DB)
Trial Notification (Subject DB)
Investigator Enrollment (Investigator DB)
Subject and Investigator Databases

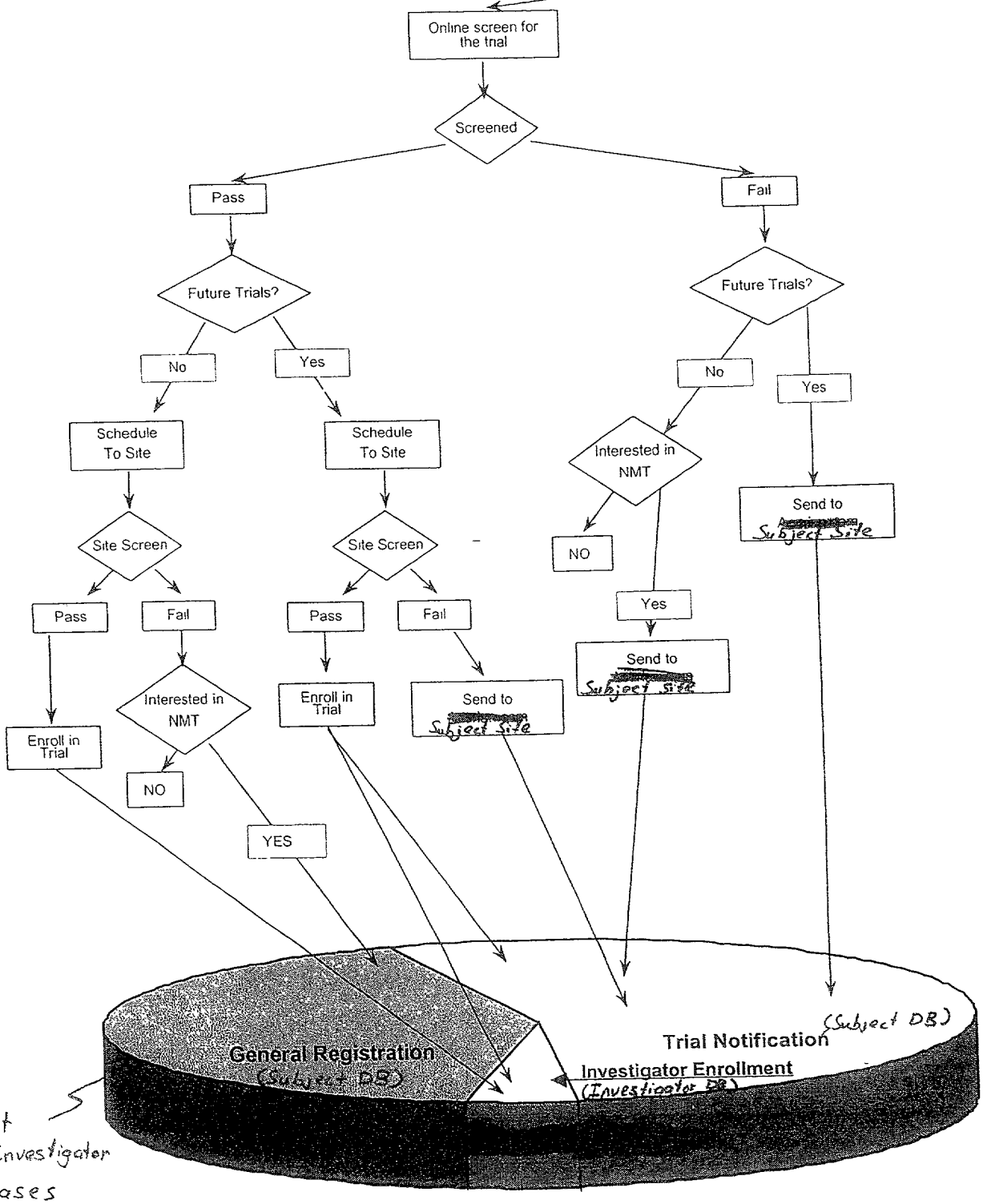


Subject and Investigator Databases

Fig. 7E


Off-Line
Call Center
Phone screen & register
Internet Access?
N
Y
Send to Subject Site
NMT or Clinical Trials
Interest in
New Medical Therapies
Clinical Trials
Search for probable trials
Future Trial Notification?
N
Y
Get Address
Send NMT Information
Get Address
Send NMT Information
Future Trial Notification?
N
Y
Trial Match?
Y
N
Phone Screened
Fail
Pass
Schedule To Site
Site Screen
Pass
Fail
Enroll
Trial Match?
Y
N
Phone Screened
Fail
Pass
Schedule To Site
Site Screen
Pass
Fail
Enroll
Store
General Registration
(Subject DB)
Trial Notification
(Subject DB)
Investigator Enrollment
(Investigator DB)
Subject and Investigator Databases

Person Visits 3rd-Party On-line Recruitment Site



Subject and Investigator Databases

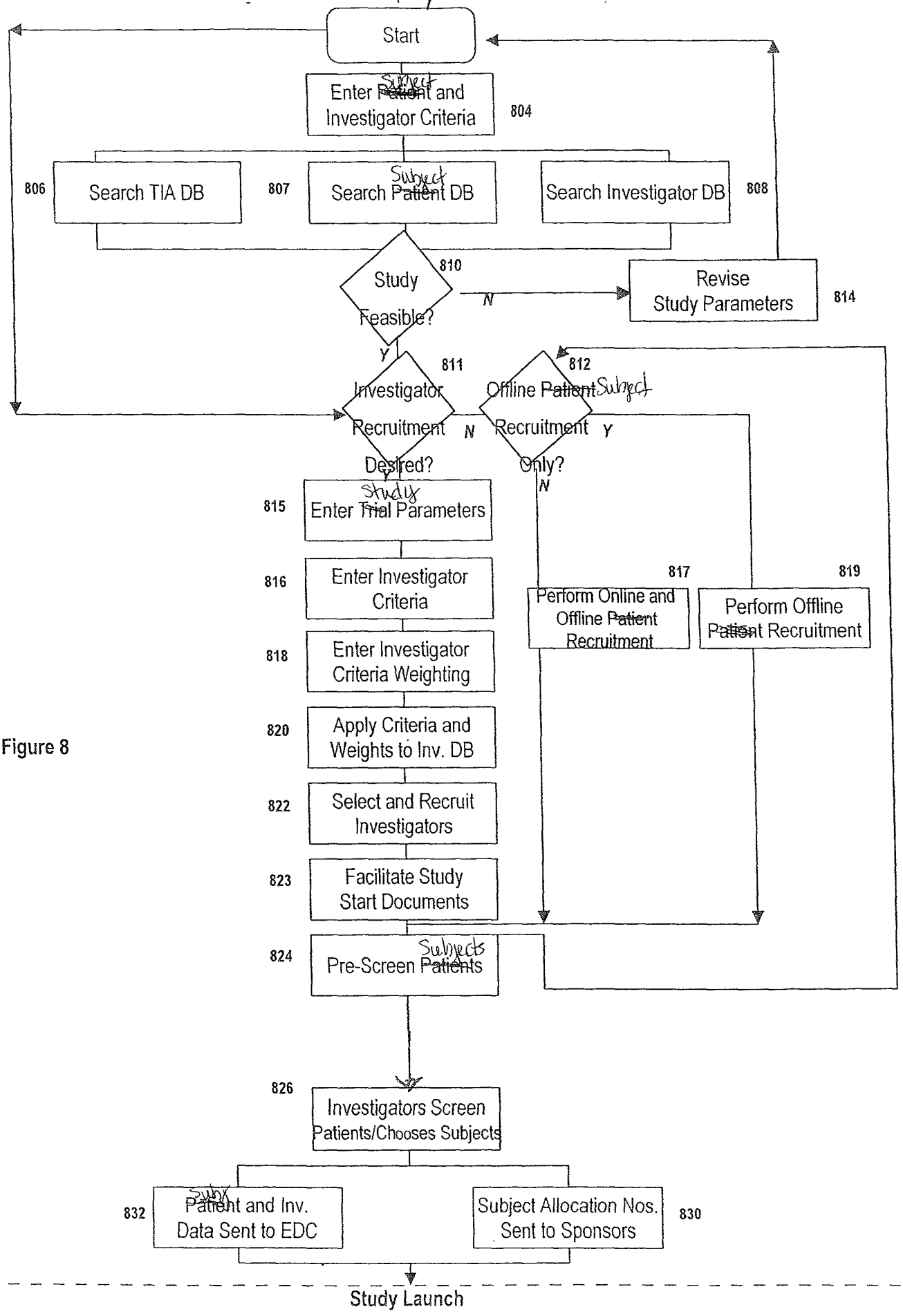

Start
Enter Patient and Investigator Criteria
804
806
Search TIA DB
807
Search Patient DB
808
Search Investigator DB
Study Feasible?
810
N
Revise Study Parameters
814
Y
811
Investigator Recruitment Desired?
812
Offline Patient Recruitment Only?
N
Y
815
Enter Trial Parameters
816
Enter Investigator Criteria
818
Enter Investigator Criteria Weighting
820
Apply Criteria and Weights to Inv. DB
822
Select and Recruit Investigators
823
Facilitate Study Start Documents
824
Pre-Screen Patients
817
Perform Online and Offline Patient Recruitment
819
Perform Offline Patient Recruitment
826
Investigators Screen Patients/Chooses Subjects
832
Patient and Inv. Data Sent to EDC
830
Subject Allocation Nos. Sent to Sponsors
Study Launch

Figure 8

Create Trial Parameters

To create an Active Trials files for a specific protocol please enter or select (from a drop down box) information to create trial parameters.

All fields required

Protocol Number

Protocol Title

Therapeutic Area --Select a Therapeutic Area--

Disease Indication --Select an Indication--

Projected Number of Sites

Projected Number of Patients per Site

Projected Trial Start Date January 2000 (Month/Year)

Projected Trial Stop Date January 2000 (Month/Year)

Projected Enrollment Period (in months)

Trial Phase -- Select Trial Phase --

Save Trial | Save & Search for Investigators

Fig. 9

Step 1:

To identify potential investigators - please select a specialty.

Addiction Psychiatry
Adolescent Medicine
Aerospace Medicine
Allergy & Immunology

Note: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections

Step 2:

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication. optional

-- No Drug Class --
Acne Therapy
Aids Therapies
All Other Misc Ethical Drugs

Note: To select more than one drug class, point to the specialty and press control click. Limit of 2 selections

Step 3:

To include the number of trials conducted by the investigator in the searcl a number. optional

1

Step 4:

To access additional databases to enhance the investigator selection proc selections below. optional

Patient Therapeutic Area

Patient Disease Indication

Patient Disease Indication Encounter Category

--Select a Category--
Case Load Estimates - Malignancy of heptobiliary system of pancreas
Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas

Note: To select more than one patient disease indication encounter category point to the specialty and press control click. Limit of 2 selections

Patient Distance from Site (in miles)

<= 3

Step 5:

To limit search by geographical location- please enter your selections belo

Municipal Area

--Select a Municipal Area --

Fig. 10

39/89

Welcome

Protocol Number
1294-5678

- Register
- Services
- FAQ
- Security & Privacy Policy
- Active Trials
- Create Trial

Home / Active Trials / Trial At A Glance / Search

Investigator Search Results

The following investigator search results reflect the investigator search criteria and the patient demographic data selected in the Investigator Search. Review selections by scrolling down this page or by clicking here: Investigator Search Criteria Summary. Click a column heading to sort by that column

Displaying 1-20 out of 682 results

Search Results:

Name	Specialty		City, State	Point of Time	Patient Demographic Information	Prescribing Decile	Subjects
Jones, J	Cardiovascular Disease	...	SEATTLE, WA	33	10-Average Length of Stay - Angin...	1-Anticoagul...	10
Hampel, J	Cardiovascular Disease	..	LA JOLLA, CA	28	4-Average Length of Stay - Angin...	1-Anticoagul...	20
Tisco, C	Cardiovascular Disease	..	SALT LAKE CITY, UT	27	5-Average Length of Stay - Angin...	1-Anticoagul...	38
Schelber, J	Cardiovascular Disease	..	MILWAUKEE, WI	27	9-Average Length of Stay - Angin...	1-Anticoagul...	10
Tucker, J	Cardiovascular Disease	..	CINCINNATI, OH	25	36-Average Length of Stay - Angin...	10-Anticoagula...	20
Robynson, C	Cardiovascular Disease	..	MCMURRAY, PA	25	6-Average Length of Stay - Angin ..	6-Anticoagul...	10
Michelson, L	Cardiovascular Disease	..	OKLAHOMA CIT, OK	24	10-Average Length of Stay - Angin...	3-Anticoagul...	15
Kleger, B	Cardiovascular Disease	..	PITTSBURGH, PA	22	27-Average Length of Stay - Angin...	1-Anticoagul...	12
Doe, J	Cardiovascular Disease	...	SARASOTA, FL	20	7-Average Length of Stay - Angin...	7-Anticoagul...	9
Smith, S	Cardiovascular Disease	...	HILLSBORO, OR	19	2-Average Length of Stay - Angin...	3-Anticoagul...	4
Cabana, M	Cardiovascular Disease	...	FOX POINT, WI	19	4-Average Length of Stay - Angin...	1-Anticoagul...	12
Watson, T	Cardiovascular Disease	..	FORT WAYNE, IN	17	2-Average Length of Stay - Angin...	9-Anticoagul...	16
Nicholas, J	Cardiovascular Disease	...	BALTIMORE, MD	16	27-Average Length of Stay - Angin...	6-Anticoagul...	11
Hamilton, P	Cardiovascular Disease	...	DURHAM, NC	16	6-Average Length of Stay - Angin...	3-Anticoagul...	22
Tang, H	Cardiovascular Disease	...	REDONDO BEAC, CA	15	10-Average Length of Stay - Angin...	6-Anticoagul...	31
Wilcox, J	Cardiovascular Disease	..	PEORIA, IL	13	13-Average Length of Stay - Angin...	5-Anticoagul...	4
Singer, J	Cardiovascular Disease	...	SANTA ROSA, CA	13	4-Average Length of Stay - Angin...	6-Anticoagul...	1
Restrepo, A	Cardiovascular Disease	..	CHARLESTON, SC	13	5-Average Length of Stay - Angin ..	1-Anticoagul...	0
Cronsman, D	Cardiovascular Disease	...	BUFFALO, NY	12	4-Average Length of Stay - Angin...	5-Anticoagul...	6
	Cardiovascular Disease	...	SELLERSVILLE, PA	12	3-Average Length of Stay - Angin...	10-Anticoagula...	1

Next 20 >

09823615 . 070801

FIG 11

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register

contact us | help

Welcome

Log Out

Protocol Number
345678

- Register
- Services
- FAQ
- Document Summary
- Document View
- Investigator View

Home / ... / Active Trials / Trial at a Glance / Document Tracking

A multi-center study... Document Summary

Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

Eligibility | Regulatory | Financial | Vendor Info | CV / Signature | IRB | Misc

Legend:
S = Sent
R = Received
C = Completed

Investigator	Questionnaire	Cost Agreement	Trial Synopsis	Other 1	Other 2	Other 3	Other 4	Other 5	Other 6	Other 7
Smith, J.		S								
Robinson, M		S								

Investigators:
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Return to Trial at a Glance

FIG. 12

1 of 1

Welcome

Protocol Number
345678

- Register
- Services
- FAQ
- Document Summary
- Document View
- Investigator View

Document View by Investigator

Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

Feasibility | Regulatory | Financial | Vendor Info | CV / Signature | IRB | Misc

Document: Questionnaire ▼ Create New Document

Investigator	Date Sent	Date Rec'd	Date Completed
Smith J	1|27|01	1|27|01	1|28|01

Investigators:
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

FIG 13

42/89

From: Service Provider Sent: June 6, 2000
To: Ms. Moore
Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to https://www.website.com/study/zz-234567-22* and complete the study specific questionaire.

Contact service.com with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.service.com/remove

Fig. 14

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?
Yes, I am the potential study participant
Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies
No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.
- o Male
- o Female

How did you hear about this study?
- o Internet
- o Newspaper Ad
- o Newspaper Article
- o Radio Ad
- o Radio Public Service Announcement
- o TV Ad
- o TV program
- o Physician
- o Friend
- o Support Group
- o Patient Ed Materials
- o Cardiology Newsletter
- o Other, please specify: _____

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with the your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?
- o Yes
- o No

Have you experienced a deterioration in memory over at least the last 6 months?

- o Yes
- o No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- o orientation
- o judgement
- o problem solving
- o functioning in community affairs
- o functioning in home or hobbies
- o functioning in personal care

Do you live in a residential home?

- o Yes
- o No

Click the box next to the person who will serve in the role of Caregiver:

I am the Caregiver
Friend
Relative
Paid personnel
No Caregiver

1. Please enter your date of birth:

   Day Month Year (pull-down boxes)

   ❑ If female, continue with question 2
   ❑ If male, continue with question 6

2. Are you / Is (Patient) surgically sterile or post-menopausal for 1 year or more?

   - o Yes – continue with question #6
     No – continue with question #3

3. Do you / Does (Patient) have any other neurological conditions such as:

   - o Parkinson's disease
   - o Pick's disease
   - o Huntingtons chorea
   - o Down's syndrome
   - o Creutzfeldt-Jacob disease
   - o Other_____

4. Do you now or did you at any time, have one or more of the following conditions resulting in your memory or *cognitive* impairment:

FIG. 15B

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- Major head injury
- Injury caused by trauma such as boxing
- Vitamin deficiency
  - Type [drop down menu]
- Brain abscess
- Syphilis
- Meningitis
- AIDS
- Brain cancer
- Thyroid, parathyroid, or pituitary disease
- Cushing's syndrome
- Kidney failure
- Uncontrolled diabetes
- Mental retardation

5. Do you have a history of any of the following:

- Stroke within the past 12 months
- Epilepsy or convulsions (Childhood convulsions caused by fever continue)
- Major depression
- Stomach ulcer that is currently being treated
- Liver, kidney, or lung disease
- Kidney stones

6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months?

- No
- Yes

7. Do you experience angina (chest pain) that required a change in medication in the past 3 months?

- Yes
- No

8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute?

- Yes
- No

9. Do you take medication for high blood pressure or chronic low blood pressure?
   - Yes
     - Medication(s) taken: [drop down menu]
   - No
   - Don't know

FIG. 15C

10. Do you take any medications for the purpose of treating memory loss such as dementia?
    - o Yes
    - o No

11. Are you allergic to any medications?
    - o Yes
        - o Which Medication(s) [drop down menu]
    - o No

12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba?
    - o Yes
        - o Which Medication(s) [drop down menu]
    - o No

13. Have you ever been enrolled in a research study for galantamine?
    - o Yes
    - o No
    - o Don't know

14. Have you taken an investigational drug in the past 30 days or are you taking one now?
    - o No, I have not taken an investigational drug in the past 30 days
    - o Yes, I have taken an investigational drug in the past 30 days
    - o Yes, am taking an investigational drug now

15. How many drinks do you consume in a typical 24-hour period?
    - o 1-2 drinks
    - o 3-5 drinks
    - o 6-8 drinks
    - o more than 8 drinks

16. Have you/patient had a CT scan or MRI of the head during the last 12 months?

    Yes
    No

FIG. 15D

SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies?

- o Yes, contact me.
- o No, I do not want to be contacted.

FIG. 15E

SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5 – 7 business days, please feel free to call the number that will be included in your mailed materials.

In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- Yes, contact me
- No, I do not want to be contacted

FIG.15F

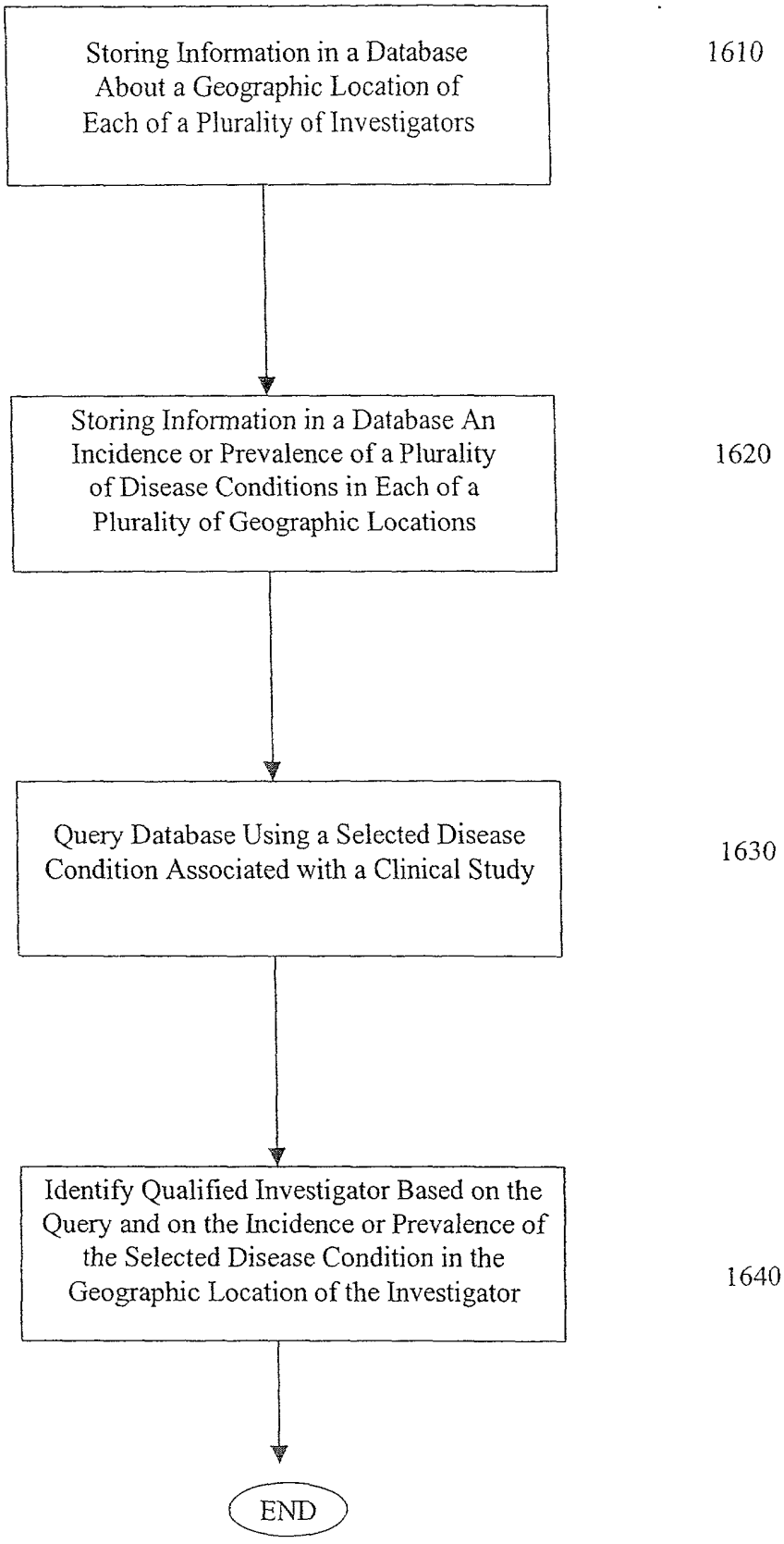

Storing Information in a Database About a Geographic Location of Each of a Plurality of Investigators
1610
Storing Information in a Database An Incidence or Prevalence of a Plurality of Disease Conditions in Each of a Plurality of Geographic Locations
1620
Query Database Using a Selected Disease Condition Associated with a Clinical Study
1630
Identify Qualified Investigator Based on the Query and on the Incidence or Prevalence of the Selected Disease Condition in the Geographic Location of the Investigator
1640
END

FIG. 16

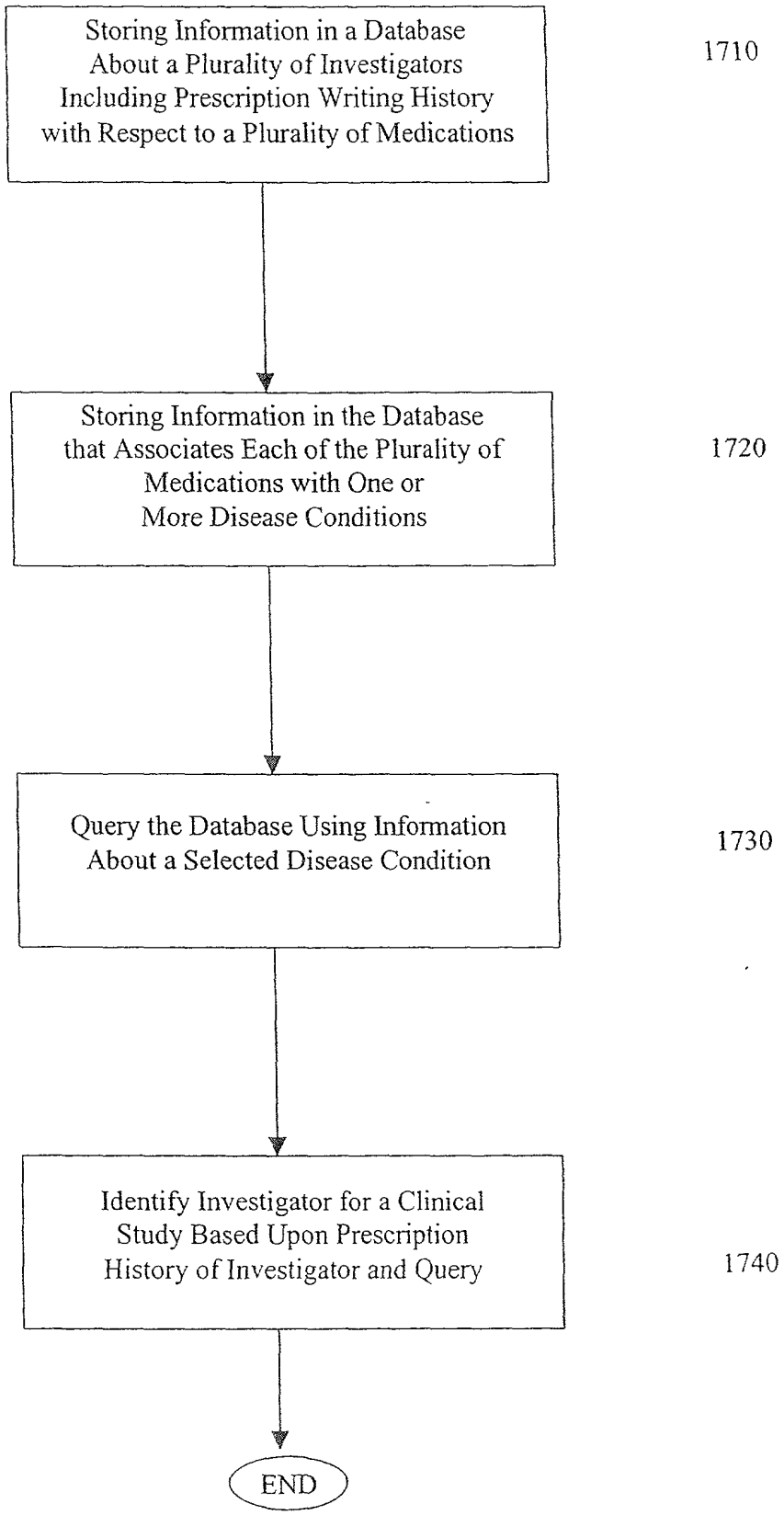


FIG. 17

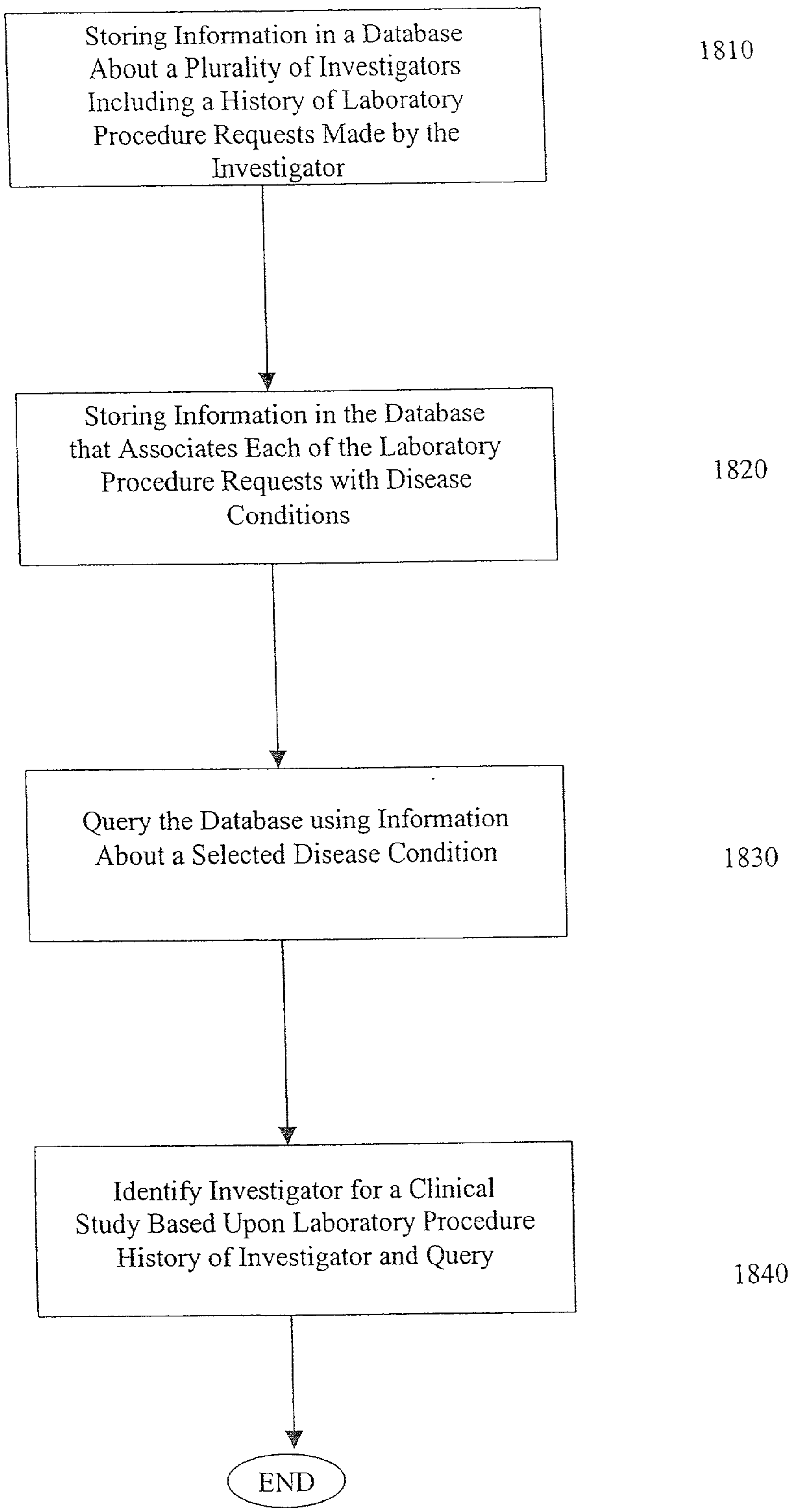

Storing Information in a Database About a Plurality of Investigators Including a History of Laboratory Procedure Requests Made by the Investigator
1810
Storing Information in the Database that Associates Each of the Laboratory Procedure Requests with Disease Conditions
1820
Query the Database using Information About a Selected Disease Condition
1830
Identify Investigator for a Clinical Study Based Upon Laboratory Procedure History of Investigator and Query
1840
END

FIG. 18

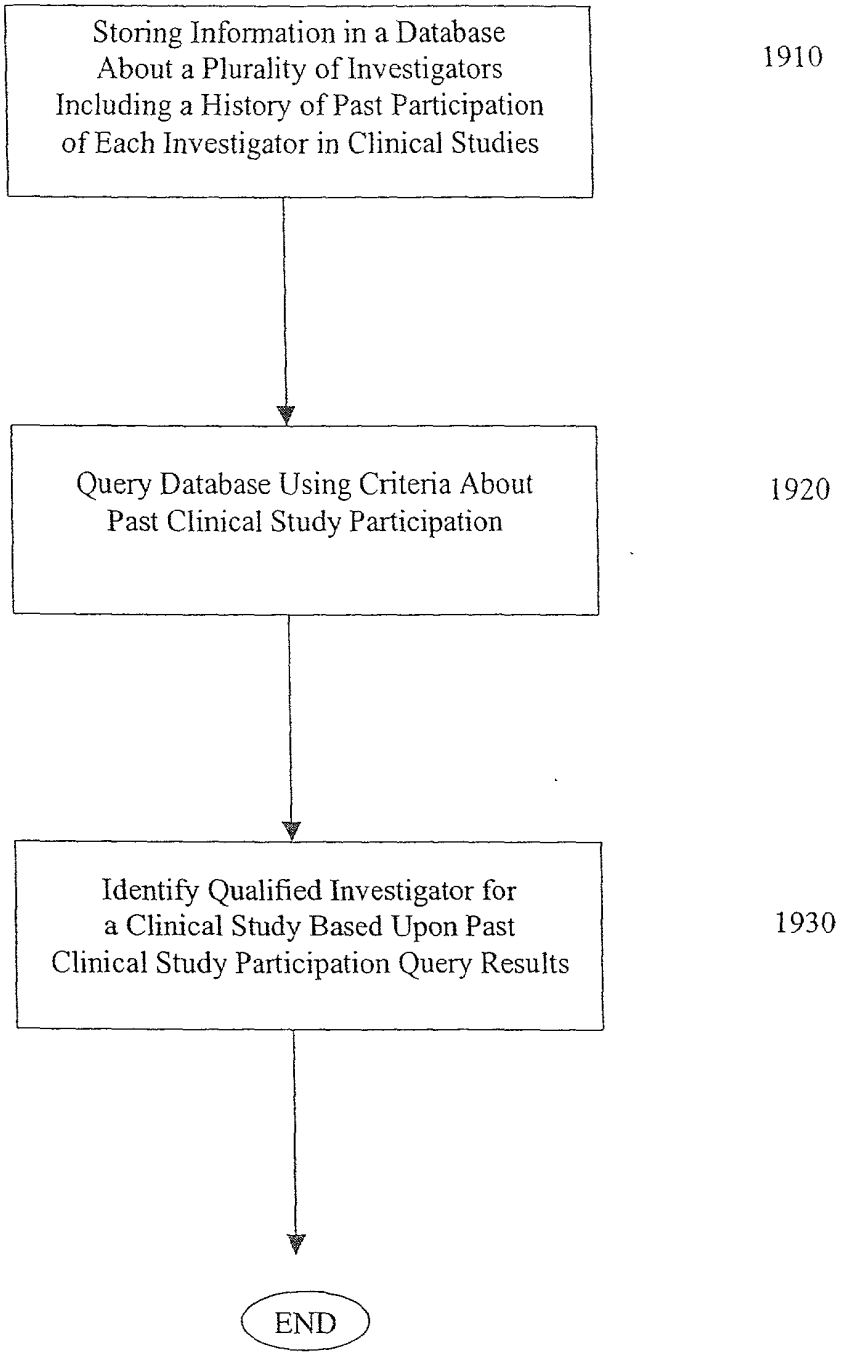
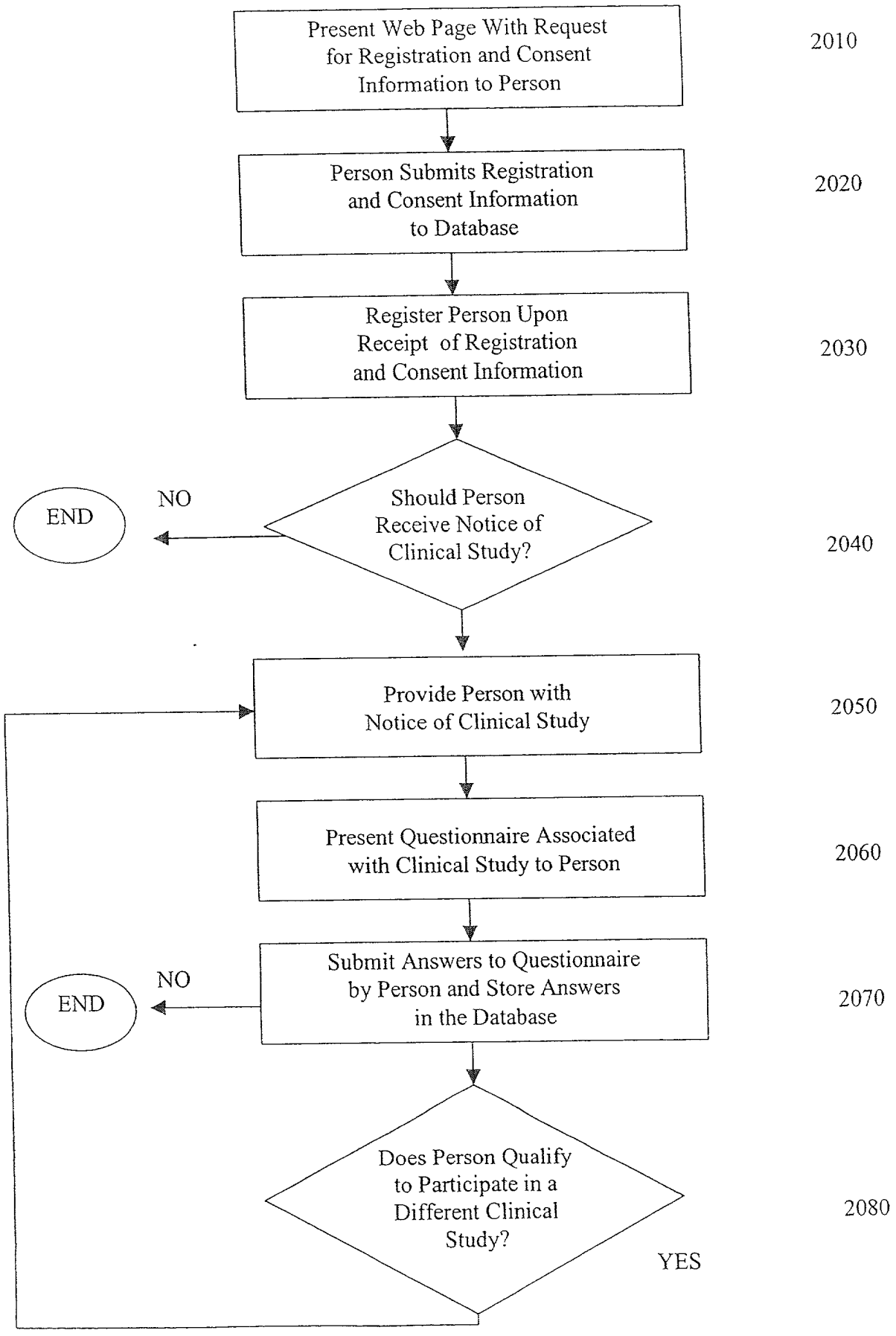

Storing Information in a Database About a Plurality of Investigators Including a History of Past Participation of Each Investigator in Clinical Studies
1910
Query Database Using Criteria About Past Clinical Study Participation
1920
Identify Qualified Investigator for a Clinical Study Based Upon Past Clinical Study Participation Query Results
1930
END

FIG. 19

FIG. 20


Present Web Page With Request for Registration and Consent Information to Person
2010
Person Submits Registration and Consent Information to Database
2020
Register Person Upon Receipt of Registration and Consent Information
2030
Should Person Receive Notice of Clinical Study?
2040
NO
END
Provide Person with Notice of Clinical Study
2050
Present Questionnaire Associated with Clinical Study to Person
2060
Submit Answers to Questionnaire by Person and Store Answers in the Database
2070
NO
END
Does Person Qualify to Participate in a Different Clinical Study?
2080
YES

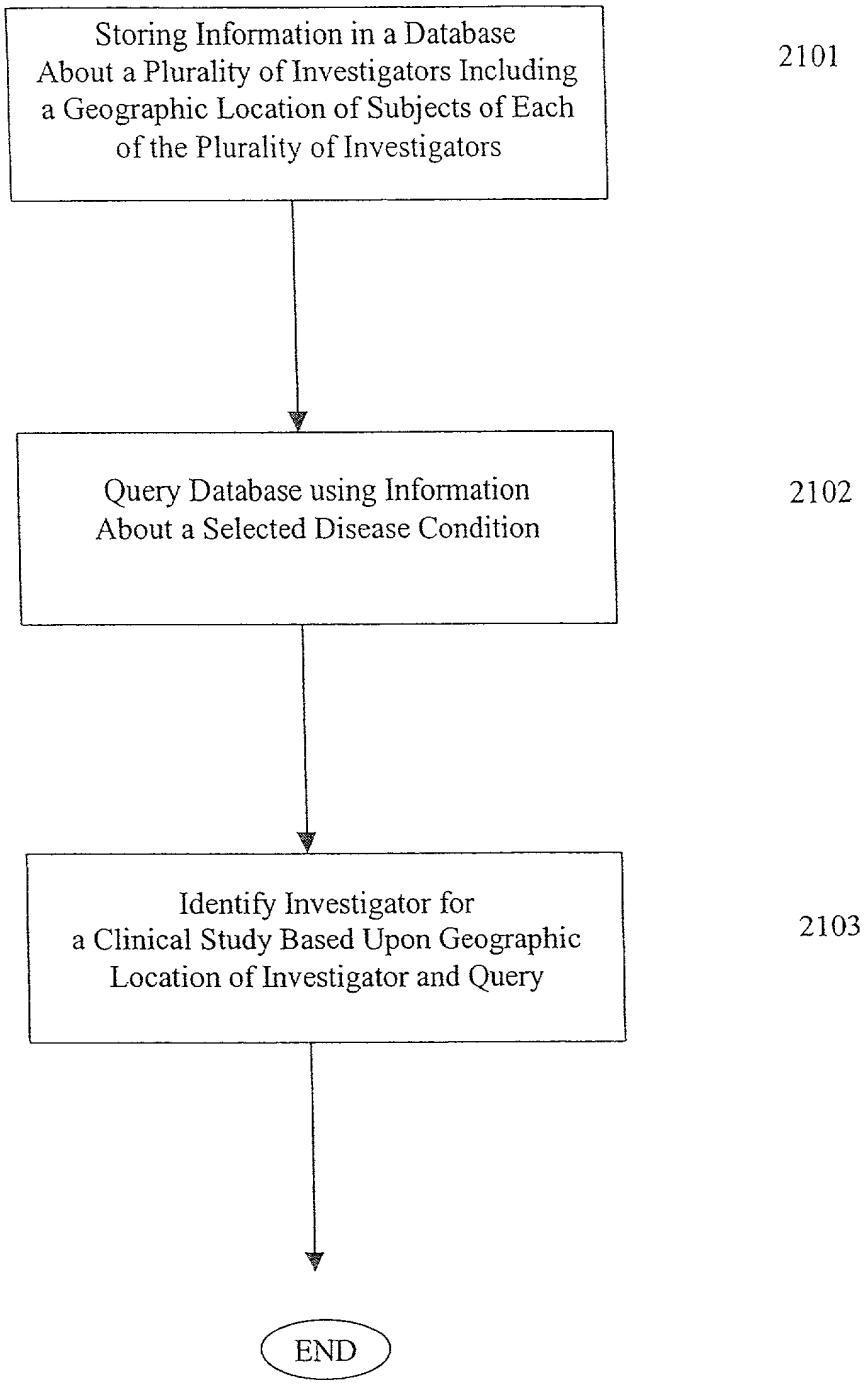

Storing Information in a Database About a Plurality of Investigators Including a Geographic Location of Subjects of Each of the Plurality of Investigators
2101
Query Database using Information About a Selected Disease Condition
2102
Identify Investigator for a Clinical Study Based Upon Geographic Location of Investigator and Query
2103
END

FIG. 21A

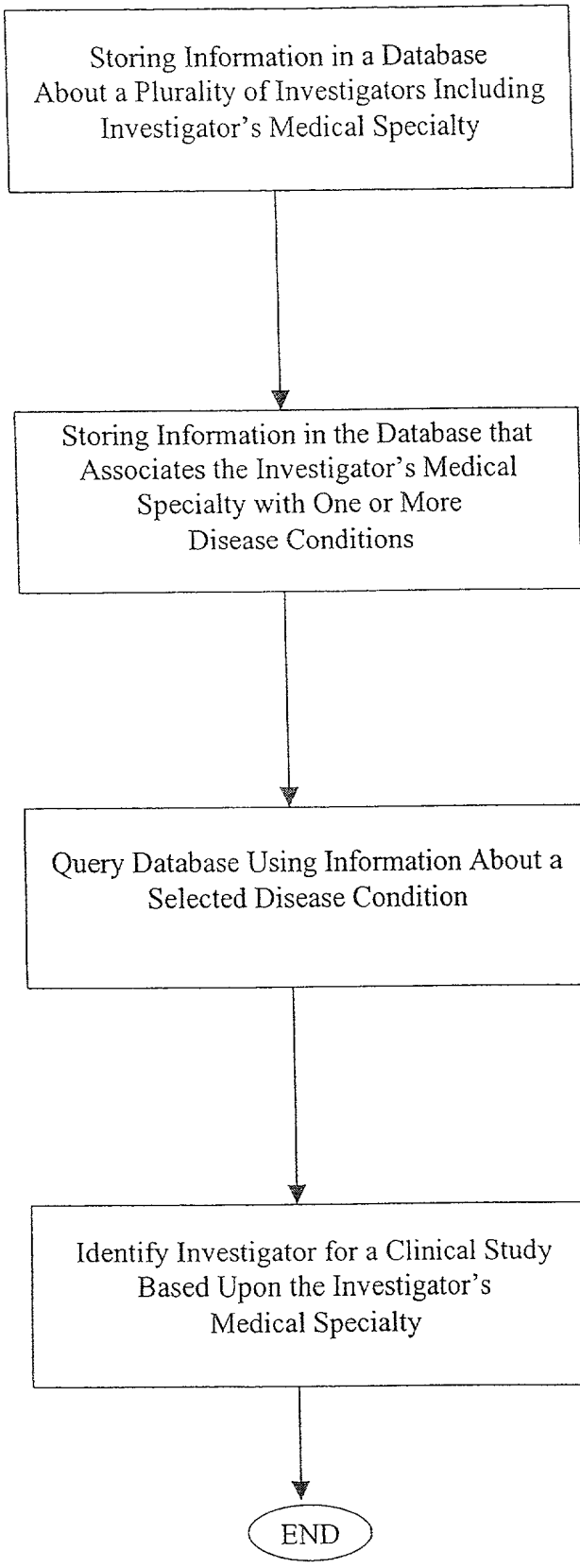

Storing Information in a Database About a Plurality of Investigators Including Investigator's Medical Specialty
2104
Storing Information in the Database that Associates the Investigator's Medical Specialty with One or More Disease Conditions
2105
Query Database Using Information About a Selected Disease Condition
2106
Identify Investigator for a Clinical Study Based Upon the Investigator's Medical Specialty
2107
END

FIG. 21B

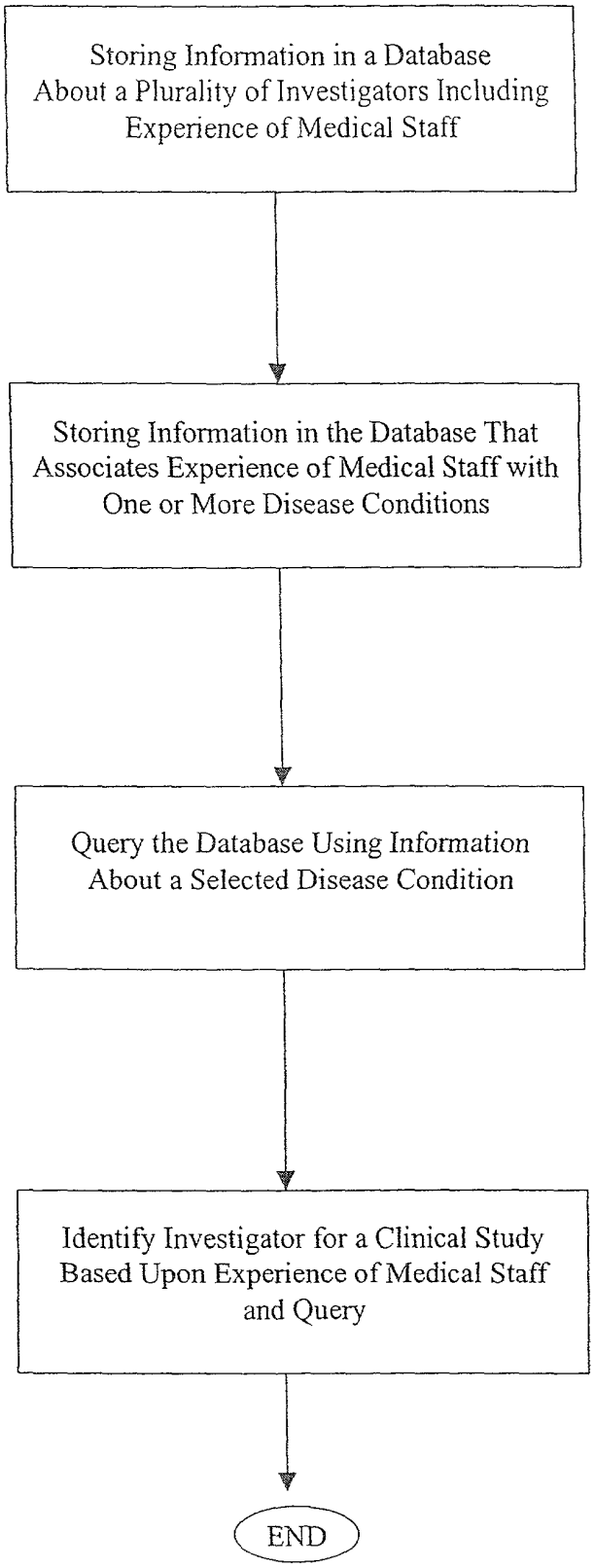

Storing Information in a Database About a Plurality of Investigators Including Experience of Medical Staff
2108
Storing Information in the Database That Associates Experience of Medical Staff with One or More Disease Conditions
2109
Query the Database Using Information About a Selected Disease Condition
2110
Identify Investigator for a Clinical Study Based Upon Experience of Medical Staff and Query
2111
END

FIG. 21C

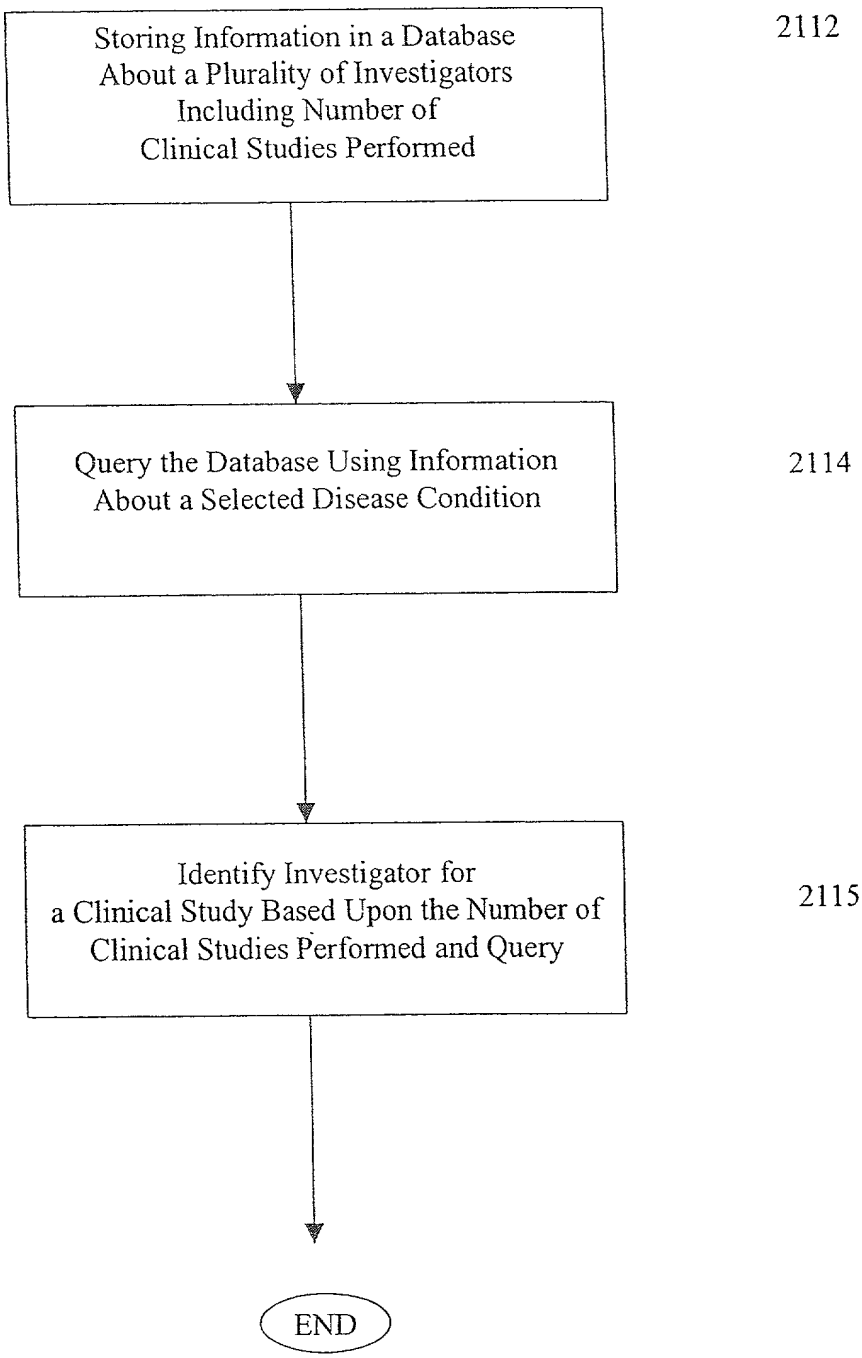

Storing Information in a Database About a Plurality of Investigators Including Number of Clinical Studies Performed
2112
Query the Database Using Information About a Selected Disease Condition
2114
Identify Investigator for a Clinical Study Based Upon the Number of Clinical Studies Performed and Query
2115
END

FIG. 21D

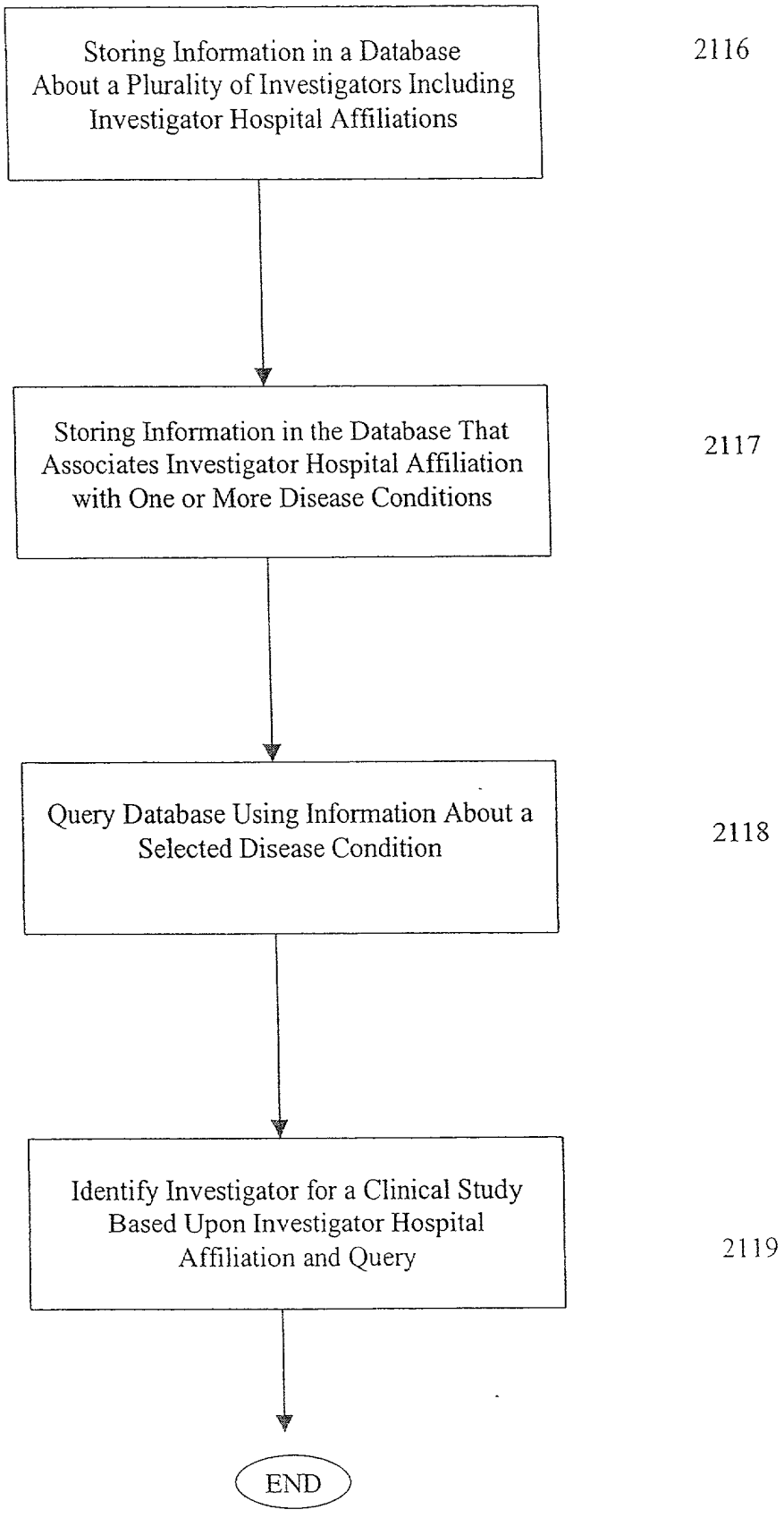


FIG. 21E

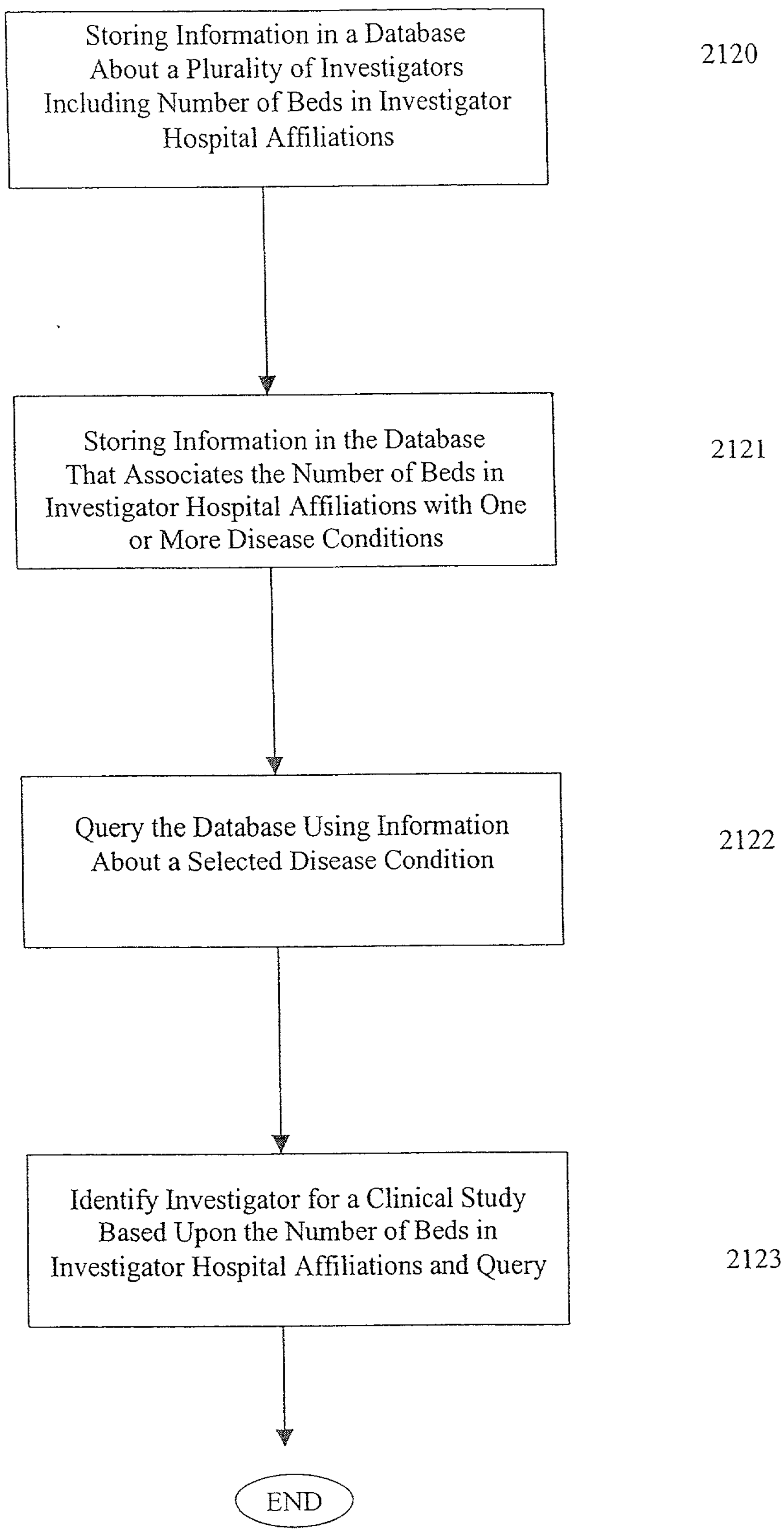

Storing Information in a Database About a Plurality of Investigators Including Number of Beds in Investigator Hospital Affiliations
2120
Storing Information in the Database That Associates the Number of Beds in Investigator Hospital Affiliations with One or More Disease Conditions
2121
Query the Database Using Information About a Selected Disease Condition
2122
Identify Investigator for a Clinical Study Based Upon the Number of Beds in Investigator Hospital Affiliations and Query
2123
END

FIG. 21F

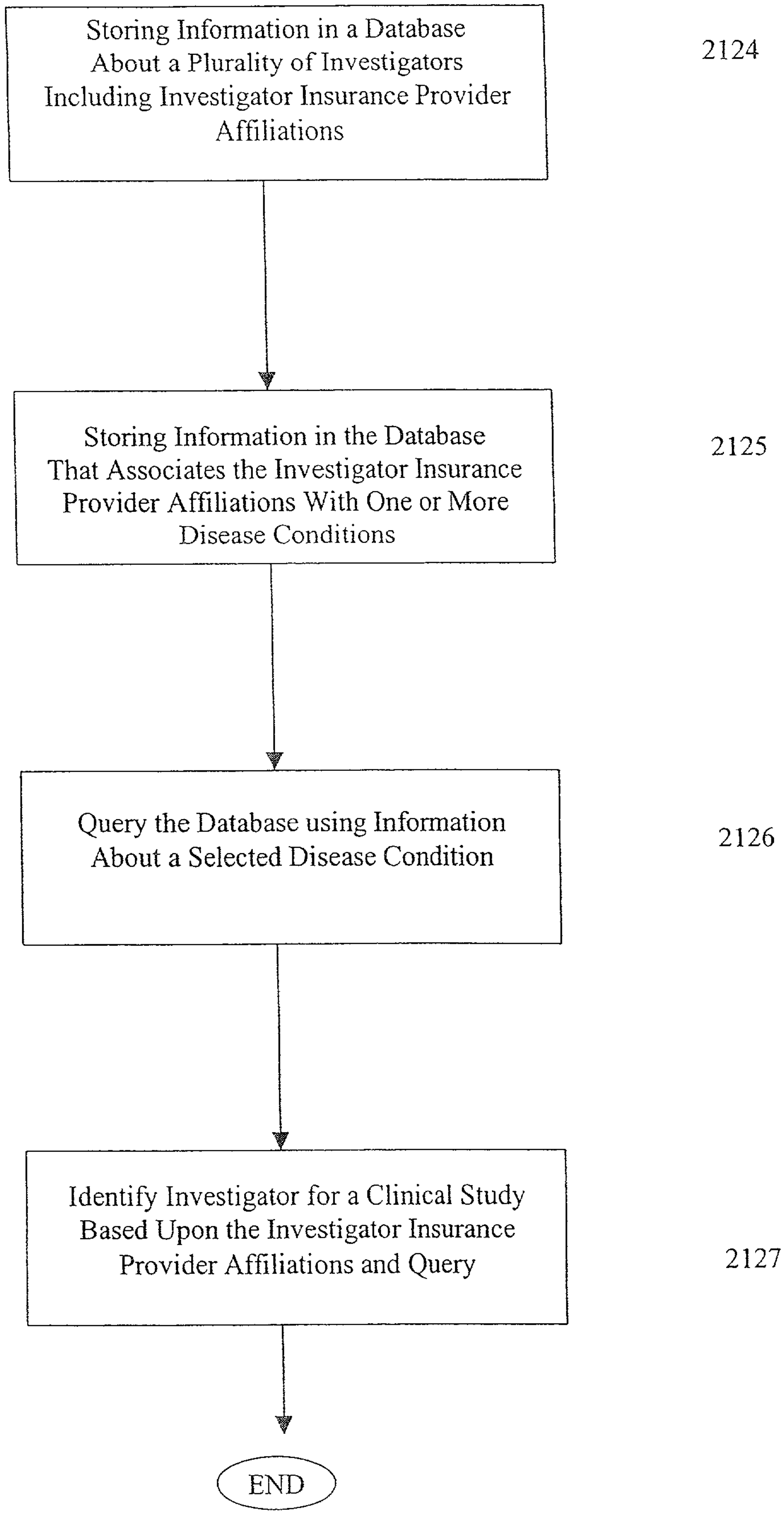

Storing Information in a Database About a Plurality of Investigators Including Investigator Insurance Provider Affiliations
2124
Storing Information in the Database That Associates the Investigator Insurance Provider Affiliations With One or More Disease Conditions
2125
Query the Database using Information About a Selected Disease Condition
2126
Identify Investigator for a Clinical Study Based Upon the Investigator Insurance Provider Affiliations and Query
2127
END

FIG. 21G

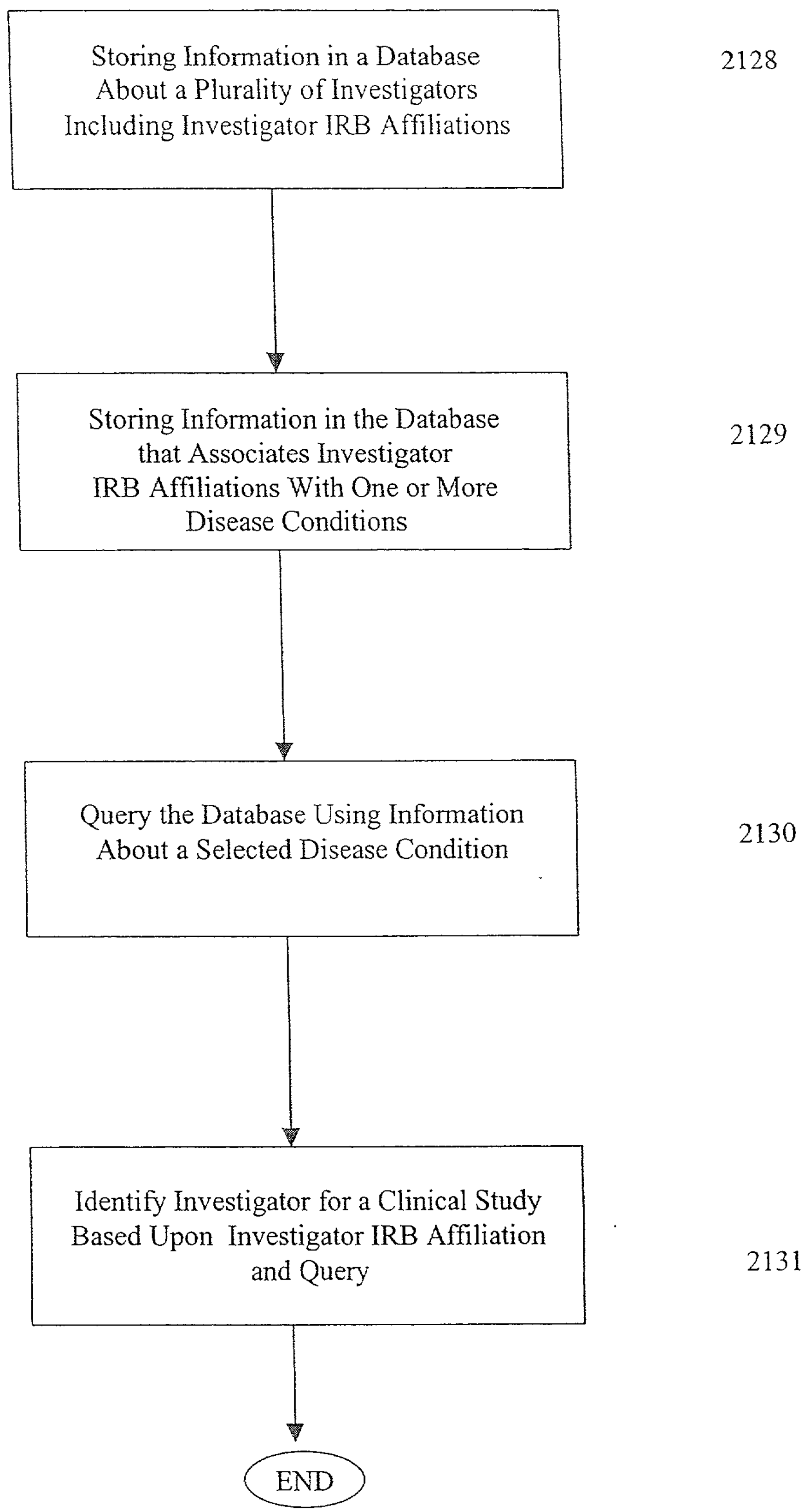

Storing Information in a Database About a Plurality of Investigators Including Investigator IRB Affiliations
2128
Storing Information in the Database that Associates Investigator IRB Affiliations With One or More Disease Conditions
2129
Query the Database Using Information About a Selected Disease Condition
2130
Identify Investigator for a Clinical Study Based Upon Investigator IRB Affiliation and Query
2131
END

FIG. 21H

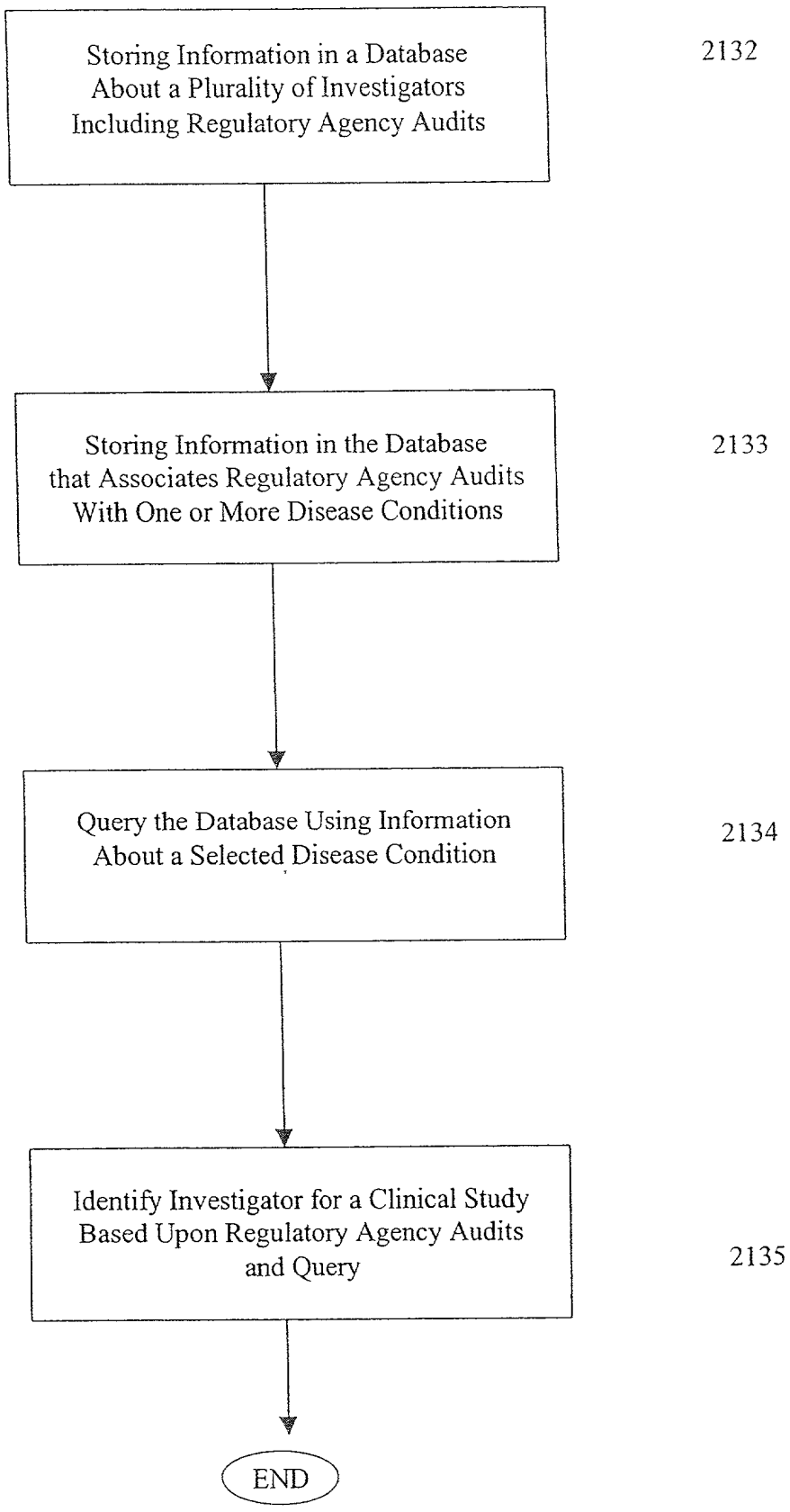


FIG. 21I

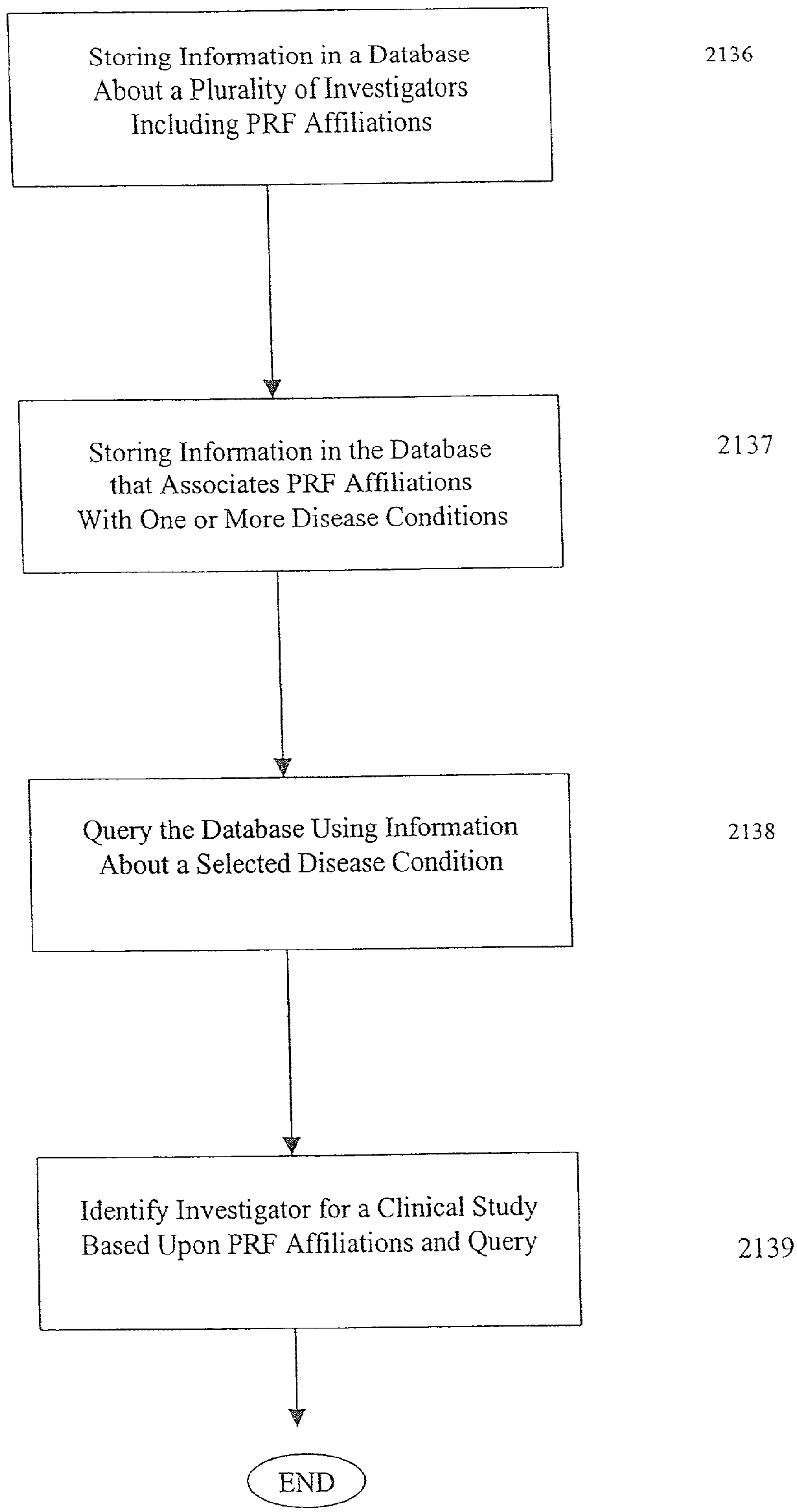

Storing Information in a Database About a Plurality of Investigators Including PRF Affiliations
2136
Storing Information in the Database that Associates PRF Affiliations With One or More Disease Conditions
2137
Query the Database Using Information About a Selected Disease Condition
2138
Identify Investigator for a Clinical Study Based Upon PRF Affiliations and Query
2139
END

FIG. 21J

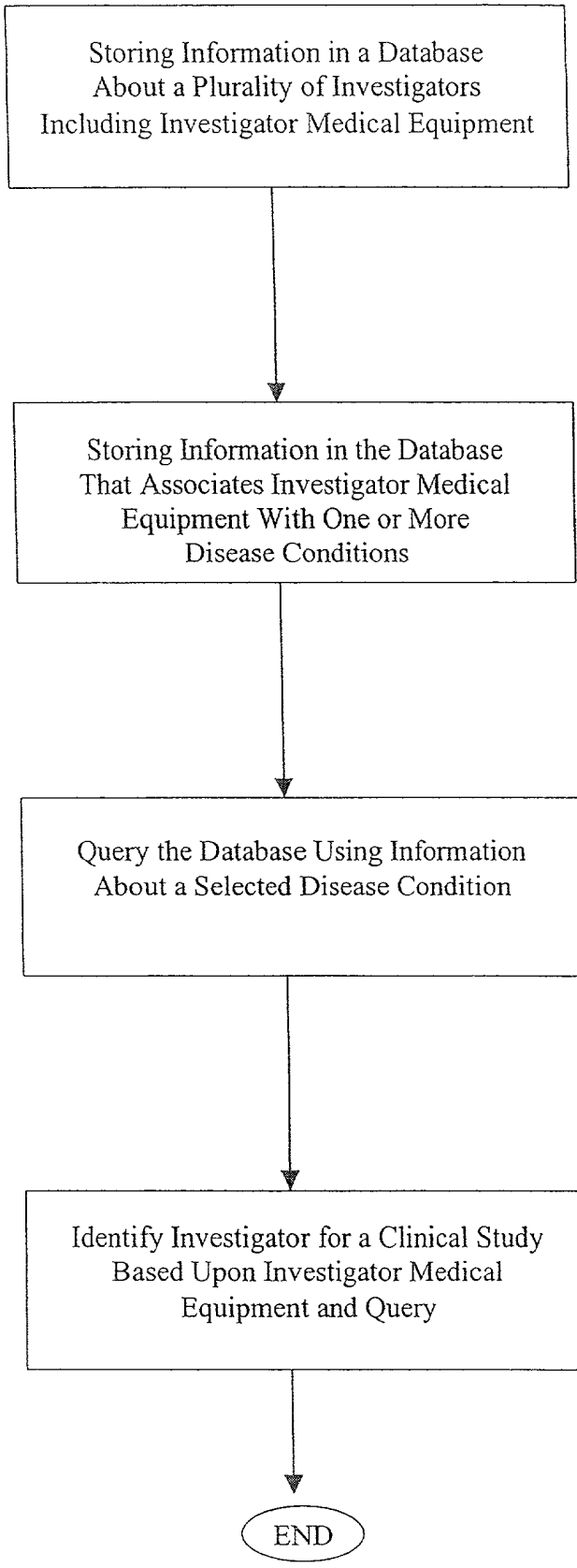

Storing Information in a Database About a Plurality of Investigators Including Investigator Medical Equipment
2140
Storing Information in the Database That Associates Investigator Medical Equipment With One or More Disease Conditions
2141
Query the Database Using Information About a Selected Disease Condition
2142
Identify Investigator for a Clinical Study Based Upon Investigator Medical Equipment and Query
2143
END

FIG. 21K

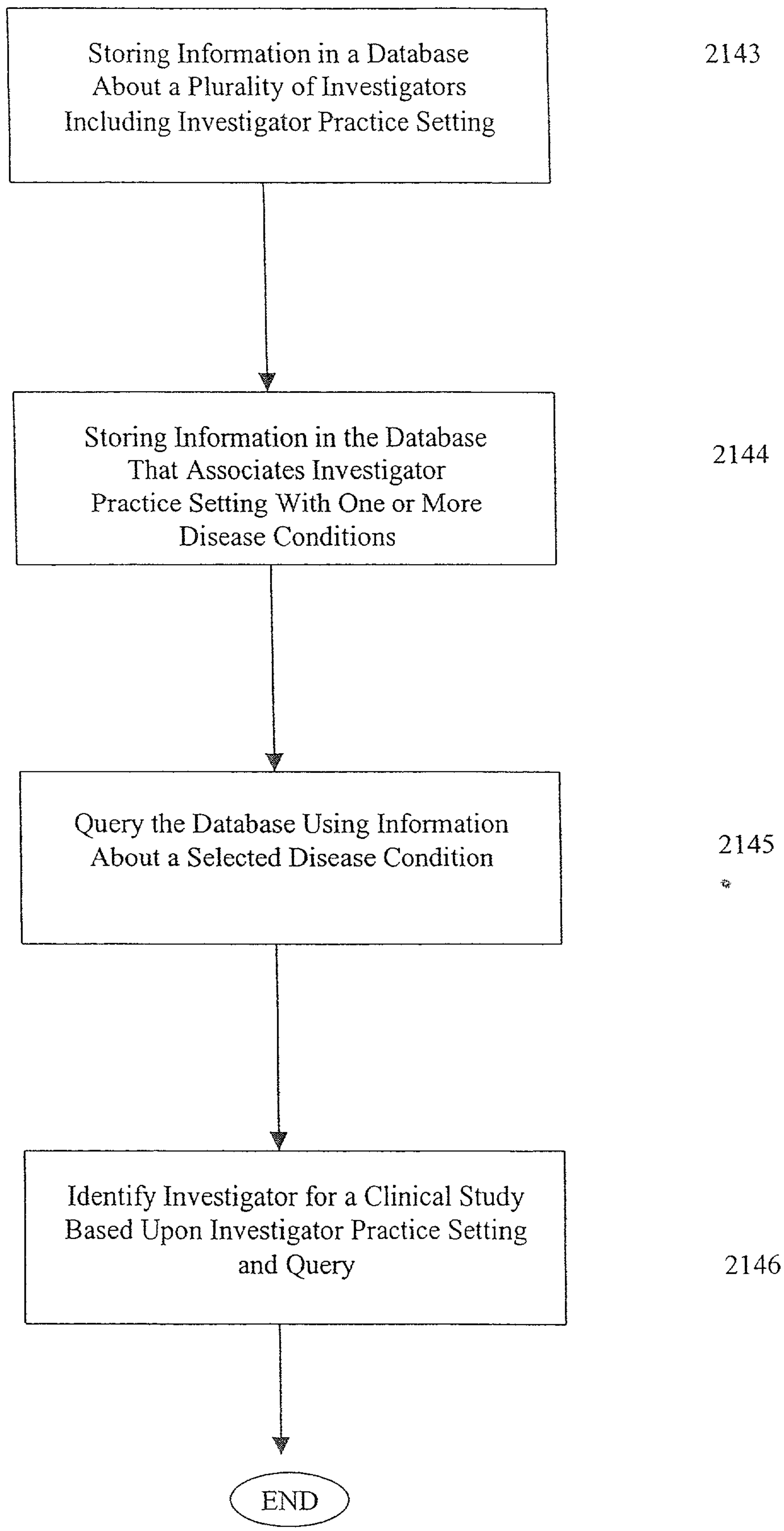


FIG. 21L

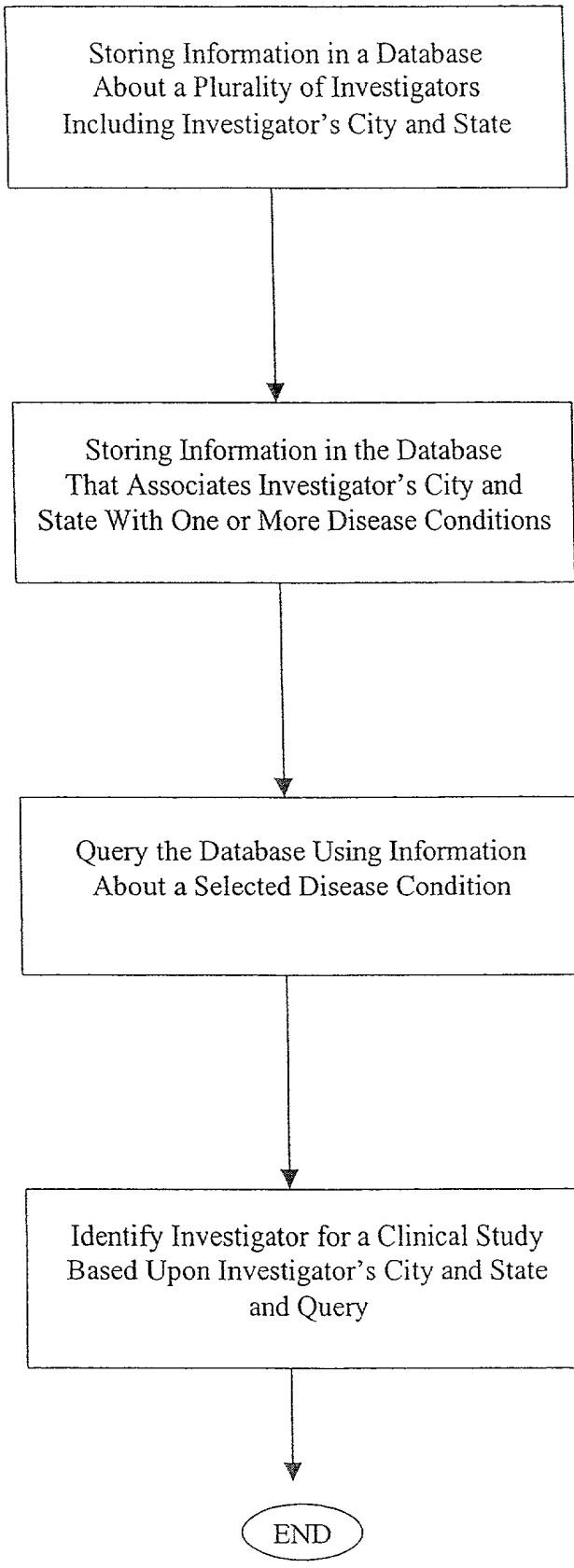

Storing Information in a Database About a Plurality of Investigators Including Investigator's City and State
2147
Storing Information in the Database That Associates Investigator's City and State With One or More Disease Conditions
2148
Query the Database Using Information About a Selected Disease Condition
2149
Identify Investigator for a Clinical Study Based Upon Investigator's City and State and Query
2150
END

FIG. 21M

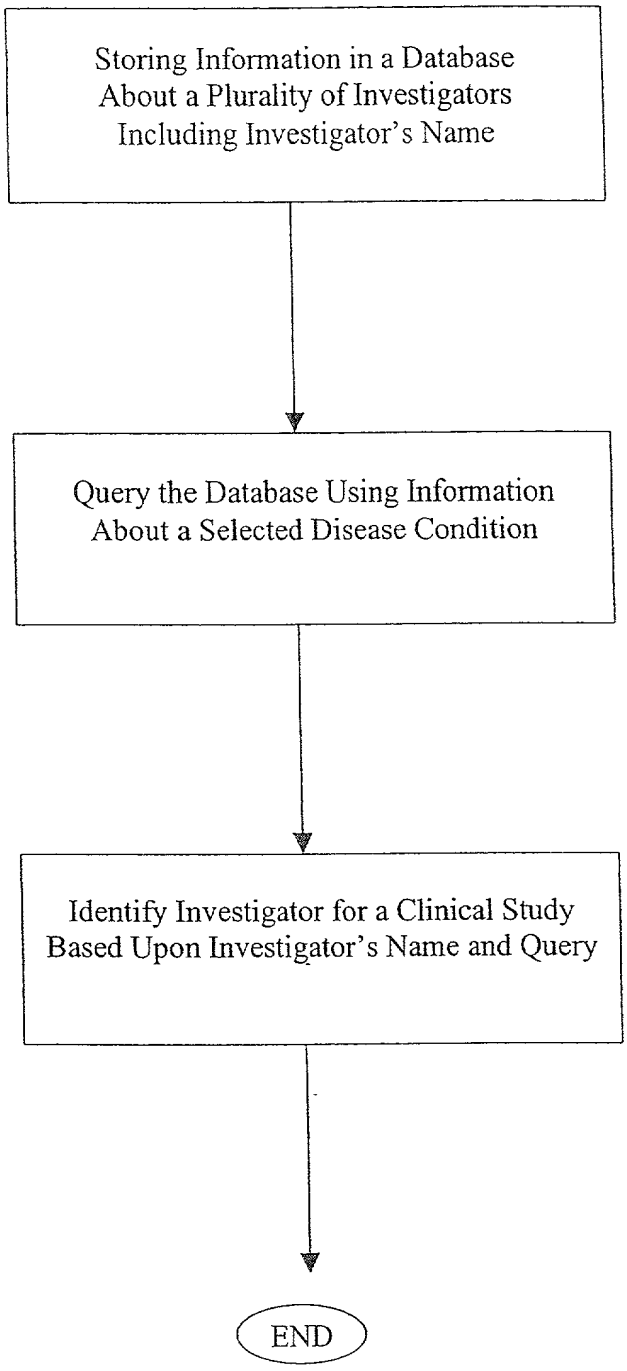

Storing Information in a Database About a Plurality of Investigators Including Investigator's Name
2151
Query the Database Using Information About a Selected Disease Condition
2152
Identify Investigator for a Clinical Study Based Upon Investigator's Name and Query
2153
END

FIG. 21N

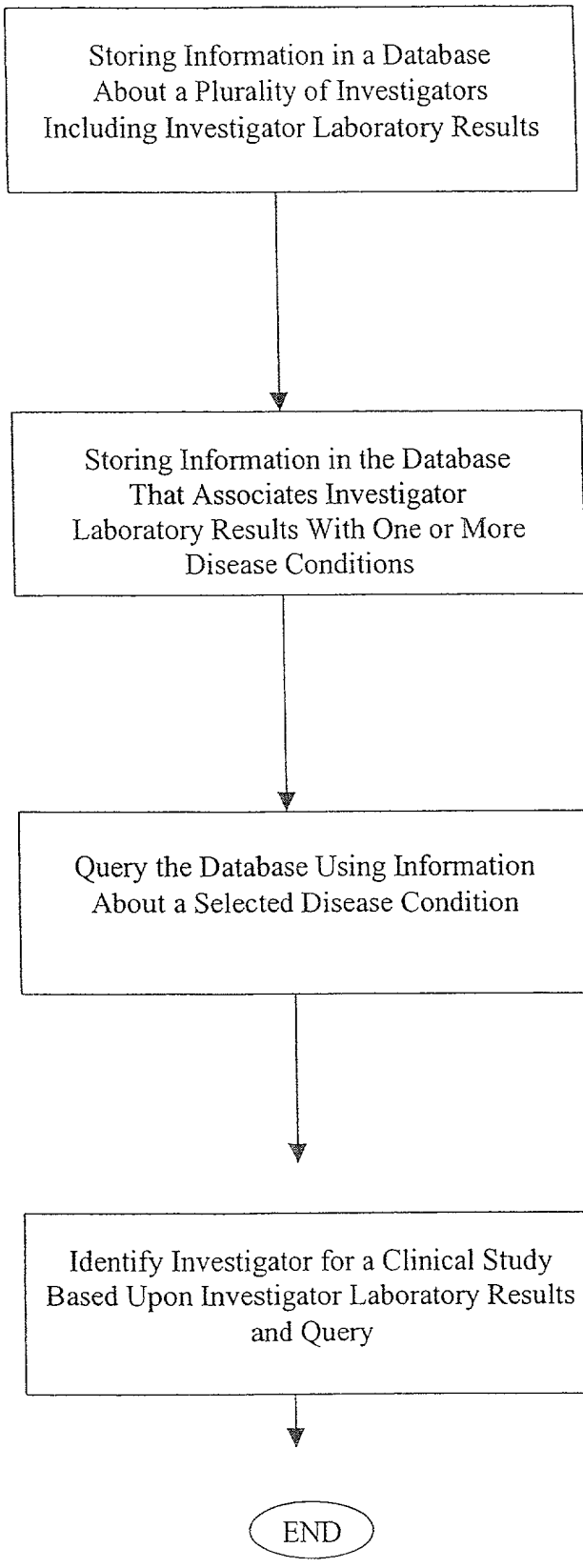

Storing Information in a Database About a Plurality of Investigators Including Investigator Laboratory Results
2154
Storing Information in the Database That Associates Investigator Laboratory Results With One or More Disease Conditions
2155
Query the Database Using Information About a Selected Disease Condition
2156
Identify Investigator for a Clinical Study Based Upon Investigator Laboratory Results and Query
2157
END

Fig. 21O

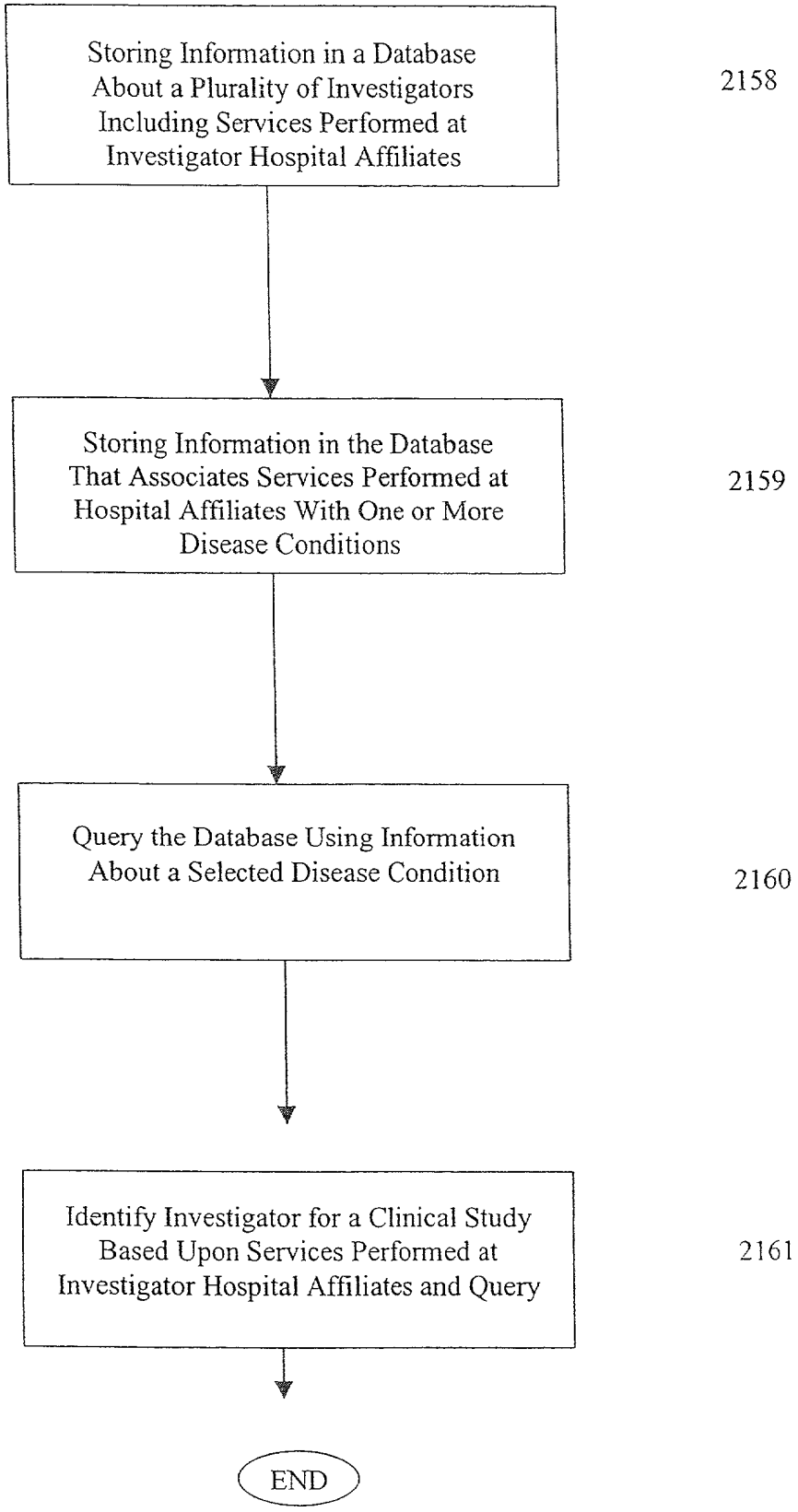

Storing Information in a Database About a Plurality of Investigators Including Services Performed at Investigator Hospital Affiliates
2158
Storing Information in the Database That Associates Services Performed at Hospital Affiliates With One or More Disease Conditions
2159
Query the Database Using Information About a Selected Disease Condition
2160
Identify Investigator for a Clinical Study Based Upon Services Performed at Investigator Hospital Affiliates and Query
2161
END

Fig. 21P

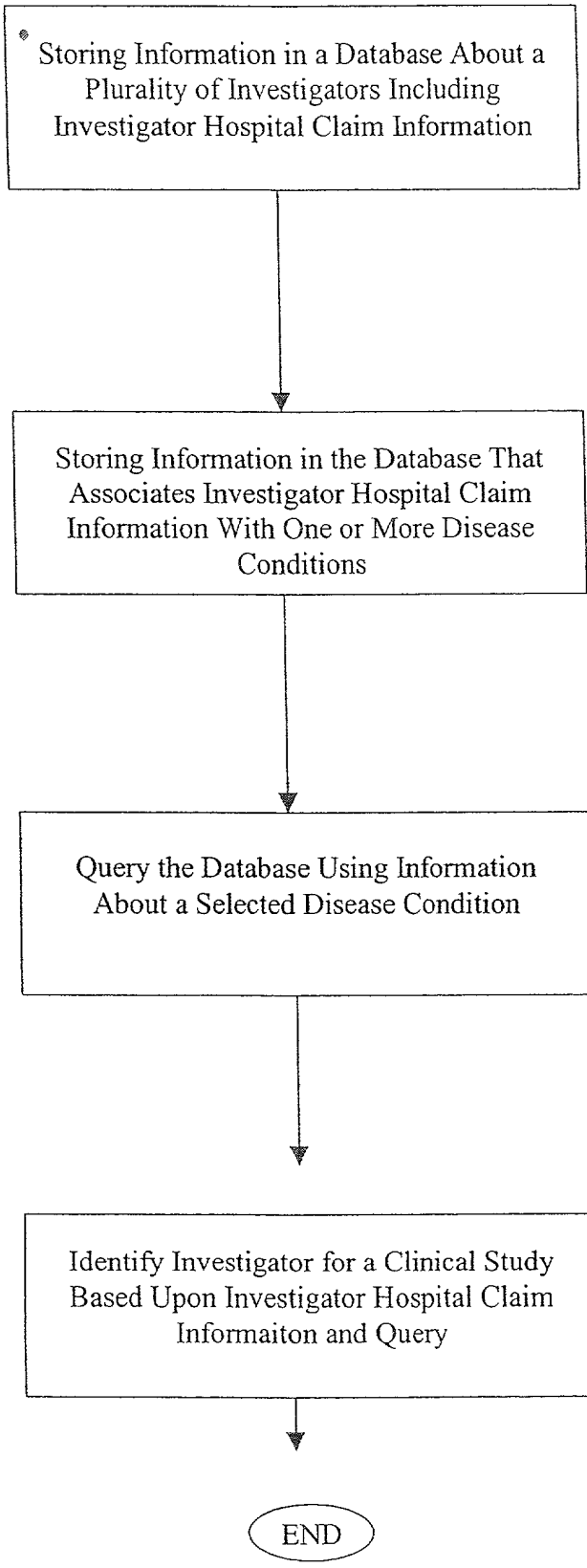
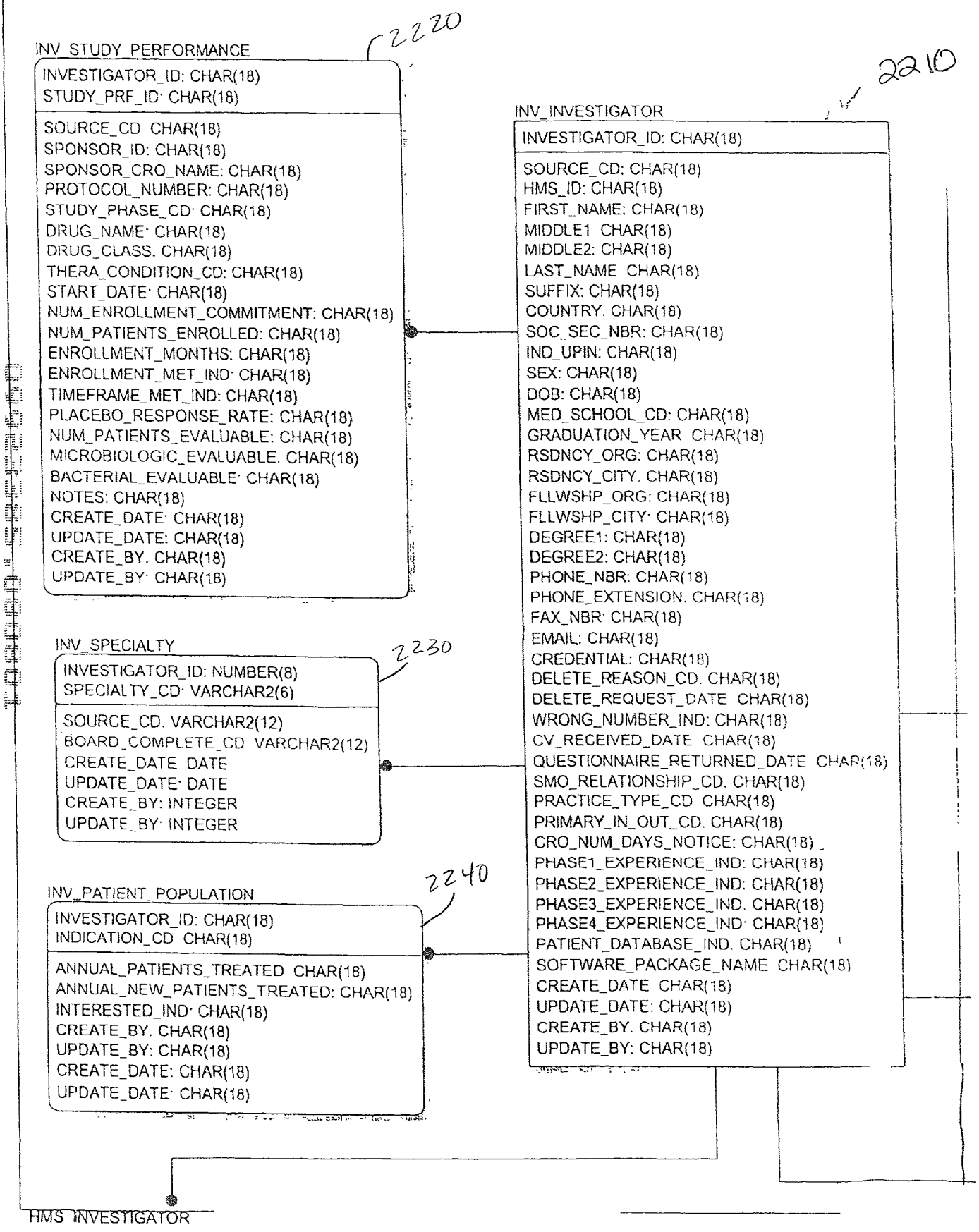
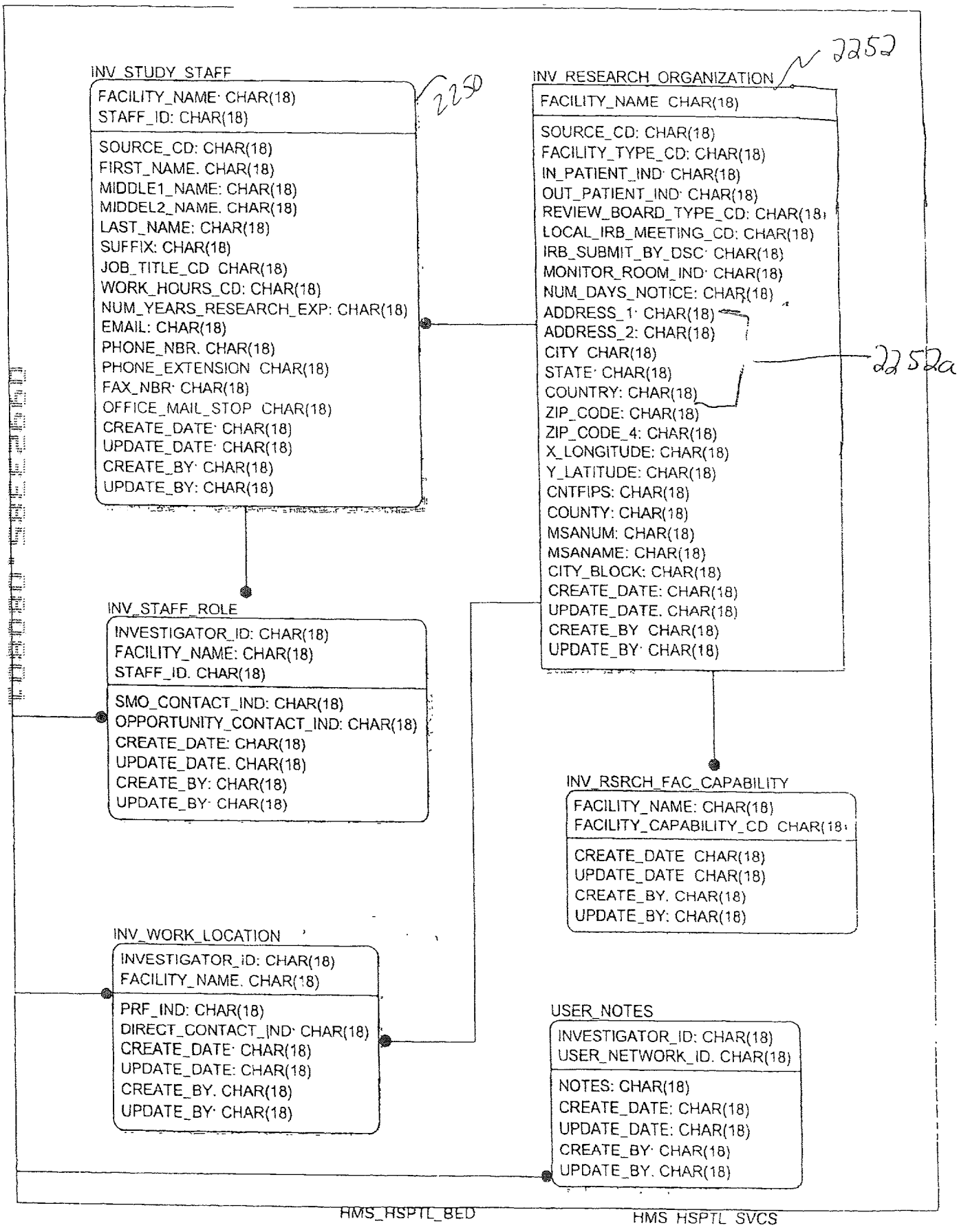

Storing Information in a Database About a Plurality of Investigators Including Investigator Hospital Claim Information
2162
Storing Information in the Database That Associates Investigator Hospital Claim Information With One or More Disease Conditions
2163
Query the Database Using Information About a Selected Disease Condition
2164
Identify Investigator for a Clinical Study Based Upon Investigator Hospital Claim Informaiton and Query
2165
END

Fig. 21Q

STLDEV01 – Display1 / Investigator

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STAFF_ID: CHAR(18)
SOURCE_CD: CHAR(18)
FIRST_NAME. CHAR(18)
MIDDLE1_NAME: CHAR(18)
MIDDEL2_NAME. CHAR(18)
LAST_NAME: CHAR(18)
SUFFIX: CHAR(18)
JOB_TITLE_CD CHAR(18)
WORK_HOURS_CD: CHAR(18)
NUM_YEARS_RESEARCH_EXP: CHAR(18)
EMAIL: CHAR(18)
PHONE_NBR. CHAR(18)
PHONE_EXTENSION CHAR(18)
FAX_NBR: CHAR(18)
OFFICE_MAIL_STOP CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
2250
INV_RESEARCH_ORGANIZATION
2252
FACILITY_NAME CHAR(18)
SOURCE_CD: CHAR(18)
FACILITY_TYPE_CD: CHAR(18)
IN_PATIENT_IND: CHAR(18)
OUT_PATIENT_IND: CHAR(18)
REVIEW_BOARD_TYPE_CD: CHAR(18)
LOCAL_IRB_MEETING_CD: CHAR(18)
IRB_SUBMIT_BY_DSC: CHAR(18)
MONITOR_ROOM_IND: CHAR(18)
NUM_DAYS_NOTICE: CHAR(18)
ADDRESS_1: CHAR(18)
ADDRESS_2: CHAR(18)
CITY CHAR(18)
STATE: CHAR(18)
COUNTRY: CHAR(18)
ZIP_CODE: CHAR(18)
ZIP_CODE_4: CHAR(18)
X_LONGITUDE: CHAR(18)
Y_LATITUDE: CHAR(18)
CNTFIPS: CHAR(18)
COUNTY: CHAR(18)
MSANUM: CHAR(18)
MSANAME: CHAR(18)
CITY_BLOCK: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE. CHAR(18)
CREATE_BY CHAR(18)
UPDATE_BY: CHAR(18)
2252a
INV_STAFF_ROLE
INVESTIGATOR_ID: CHAR(18)
FACILITY_NAME: CHAR(18)
STAFF_ID. CHAR(18)
SMO_CONTACT_IND: CHAR(18)
OPPORTUNITY_CONTACT_IND: CHAR(18)
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UPDATE_DATE. CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY: CHAR(18)
INV_RSRCH_FAC_CAPABILITY
FACILITY_NAME: CHAR(18)
FACILITY_CAPABILITY_CD CHAR(18)
CREATE_DATE CHAR(18)
UPDATE_DATE CHAR(18)
CREATE_BY. CHAR(18)
UPDATE_BY: CHAR(18)
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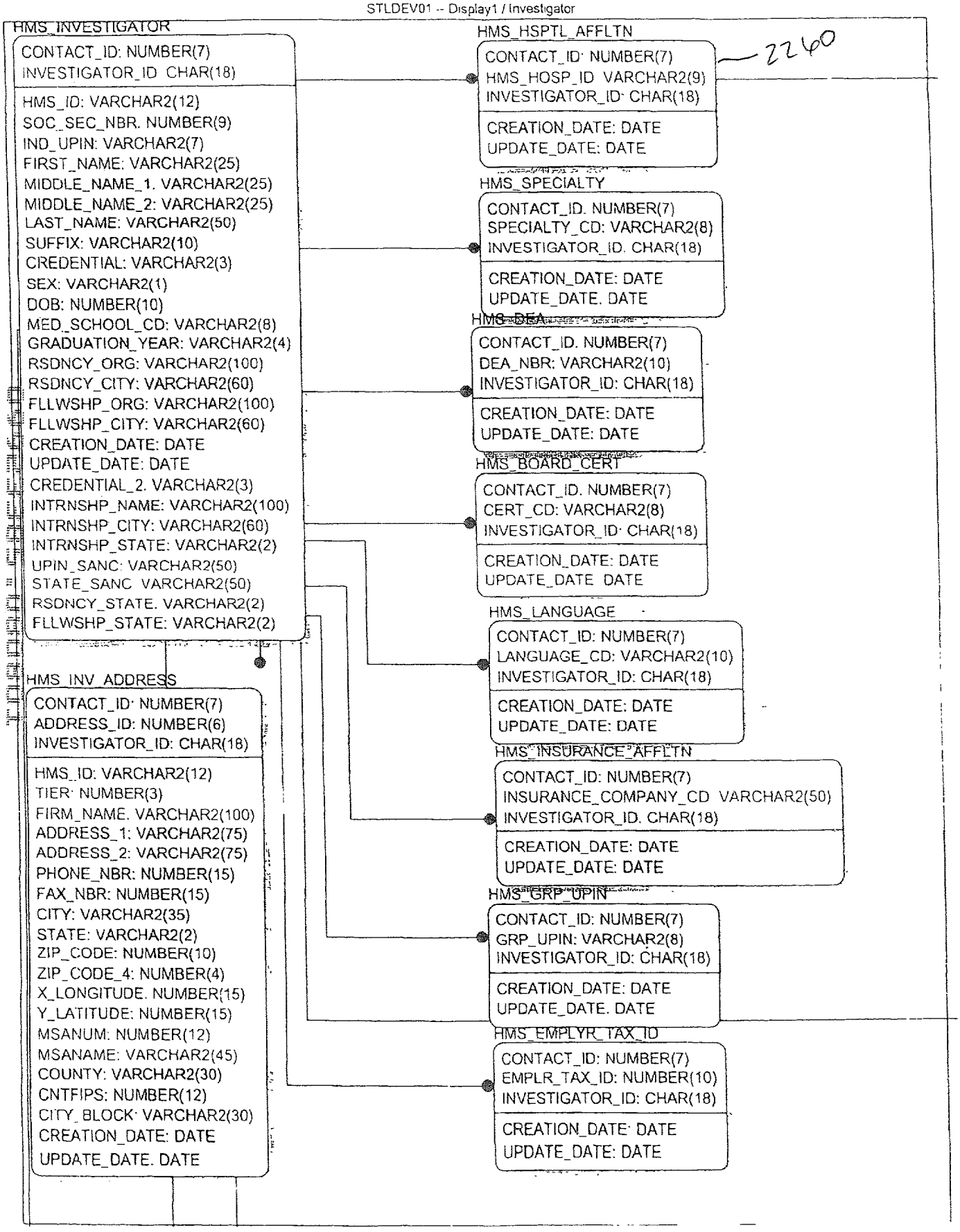
INVESTIGATOR_ID: CHAR(18)
FACILITY_NAME. CHAR(18)
PRF_IND: CHAR(18)
DIRECT_CONTACT_IND: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY. CHAR(18)
UPDATE_BY: CHAR(18)
USER_NOTES
INVESTIGATOR_ID: CHAR(18)
USER_NETWORK_ID. CHAR(18)
NOTES: CHAR(18)
CREATE_DATE: CHAR(18)
UPDATE_DATE: CHAR(18)
CREATE_BY: CHAR(18)
UPDATE_BY. CHAR(18)
HMS_HSPTL_BED
HMS HSPTL SVCS

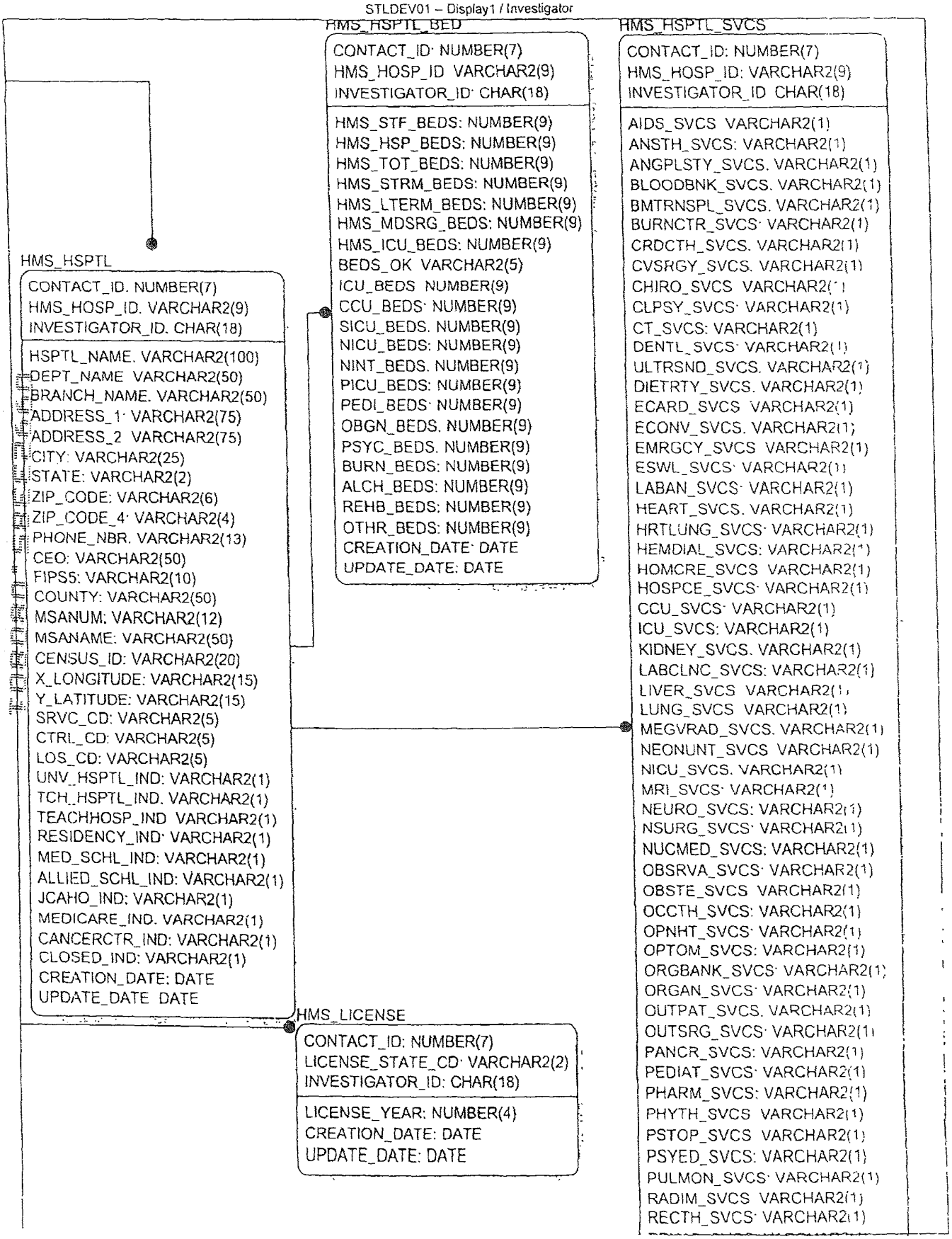
STLDEV01 -- Display1 / Investigator



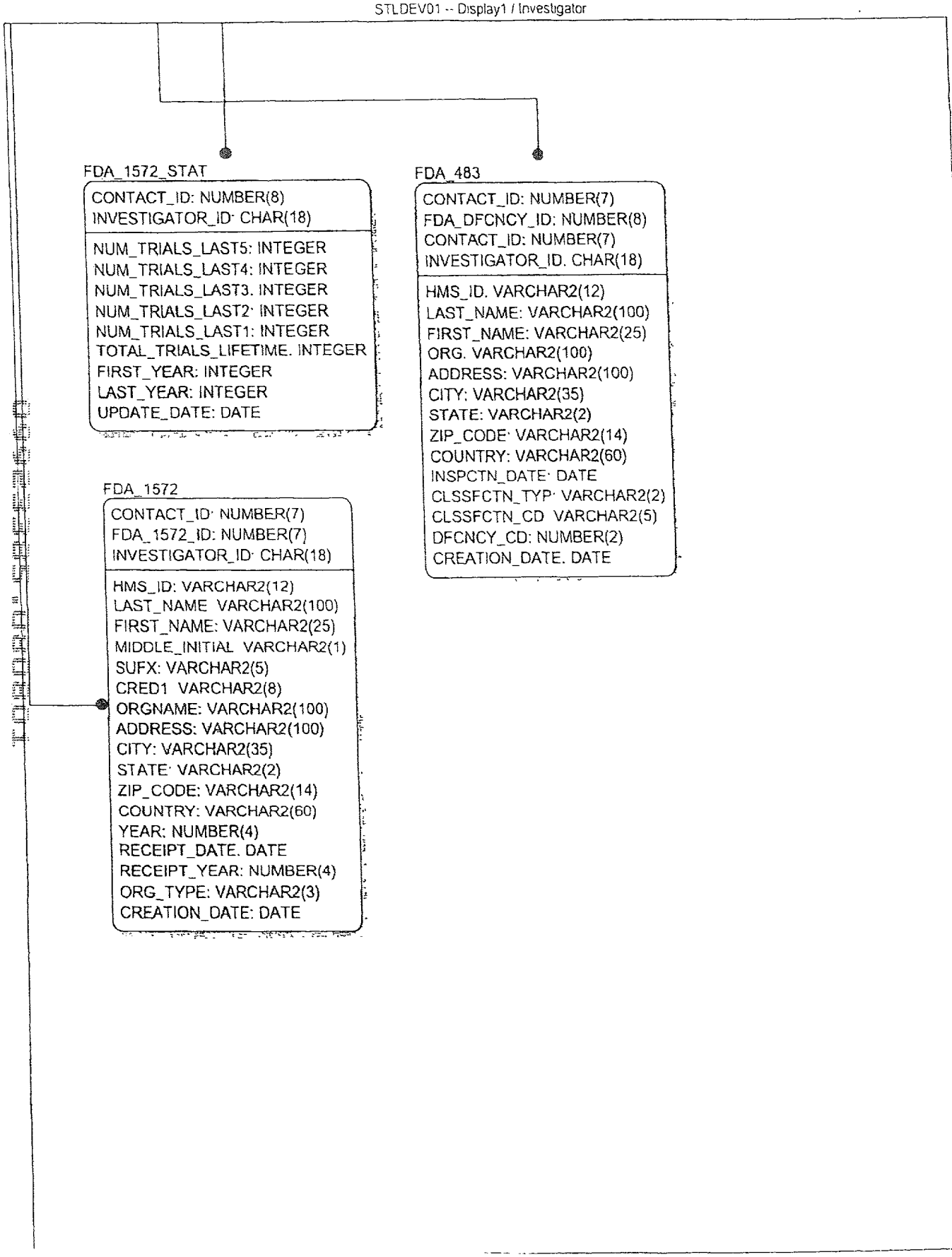
STLDEV01 – Display1 / Investigator

REHAB_SVCS: VARCHAR2(1)
RESPIR_SVCS: VARCHAR2(1)
SELFCARE_SVCS VARCHAR2(1)
SKNLT_SVCS: VARCHAR2(1)
SOCSVC_SVCS VARCHAR2(1)
SPEECH_SVCS VARCHAR2(1)
THERD_SVCS VARCHAR2(1)
TRAUMA_SVCS: VARCHAR2(1)
XRADT_SVCS VARCHAR2(1)
CREATION_DATE DATE
UPDATE_DATE: DATE

STLDEV01 – Display1 / Investigator



STLDEV01 -- Display1 / Investigator



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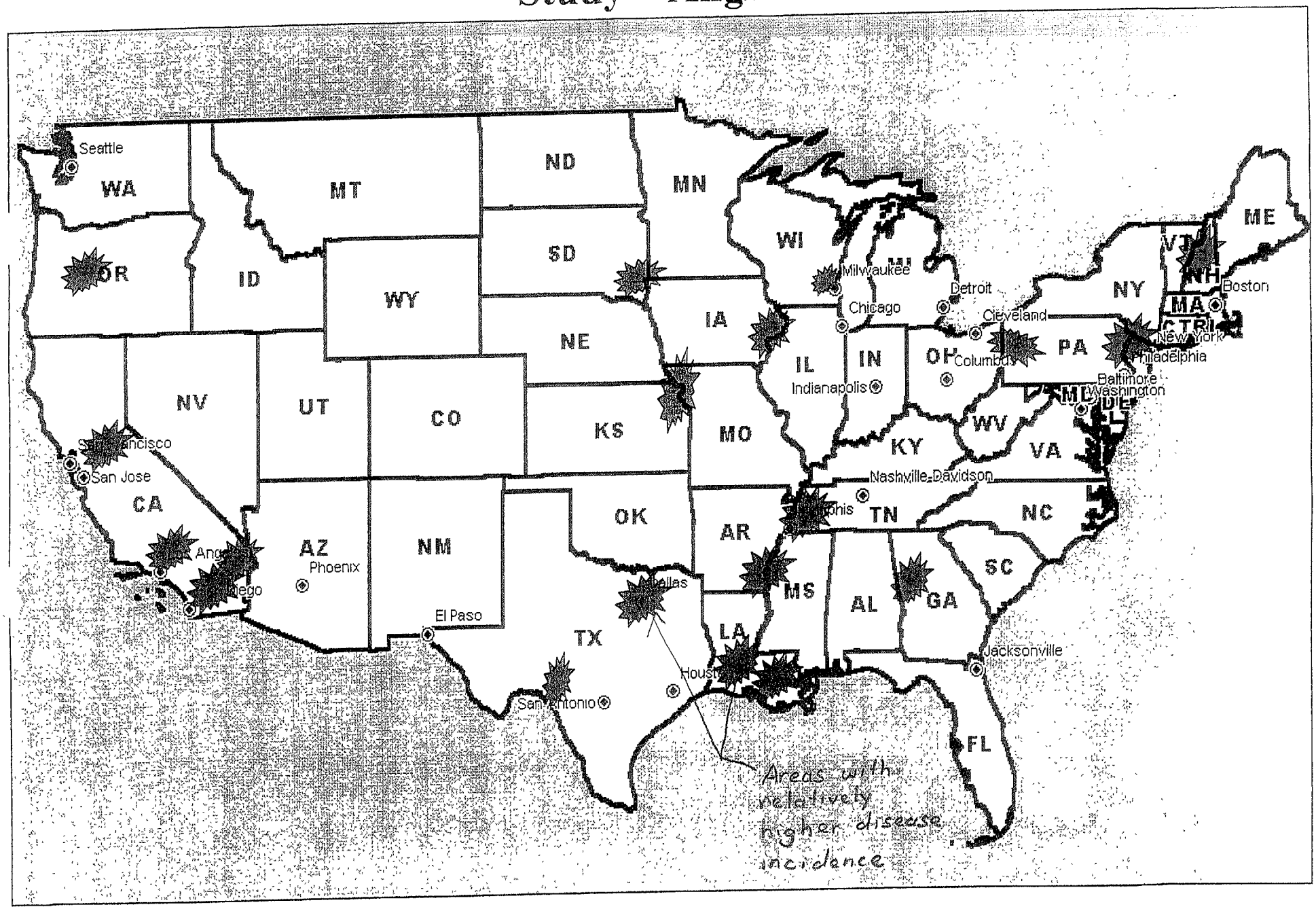
Step 1 Disease Incidence Search

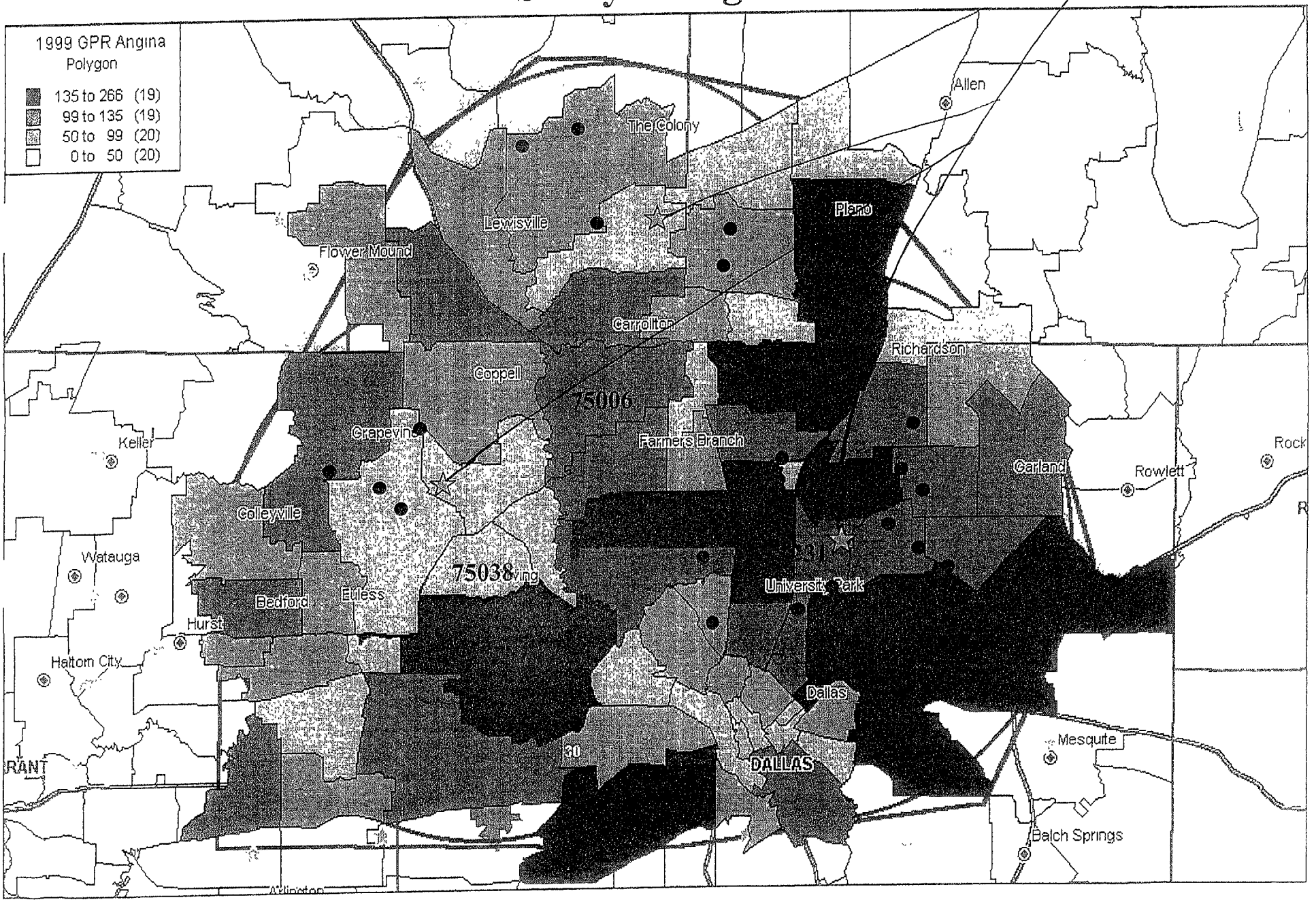
Study – Angina



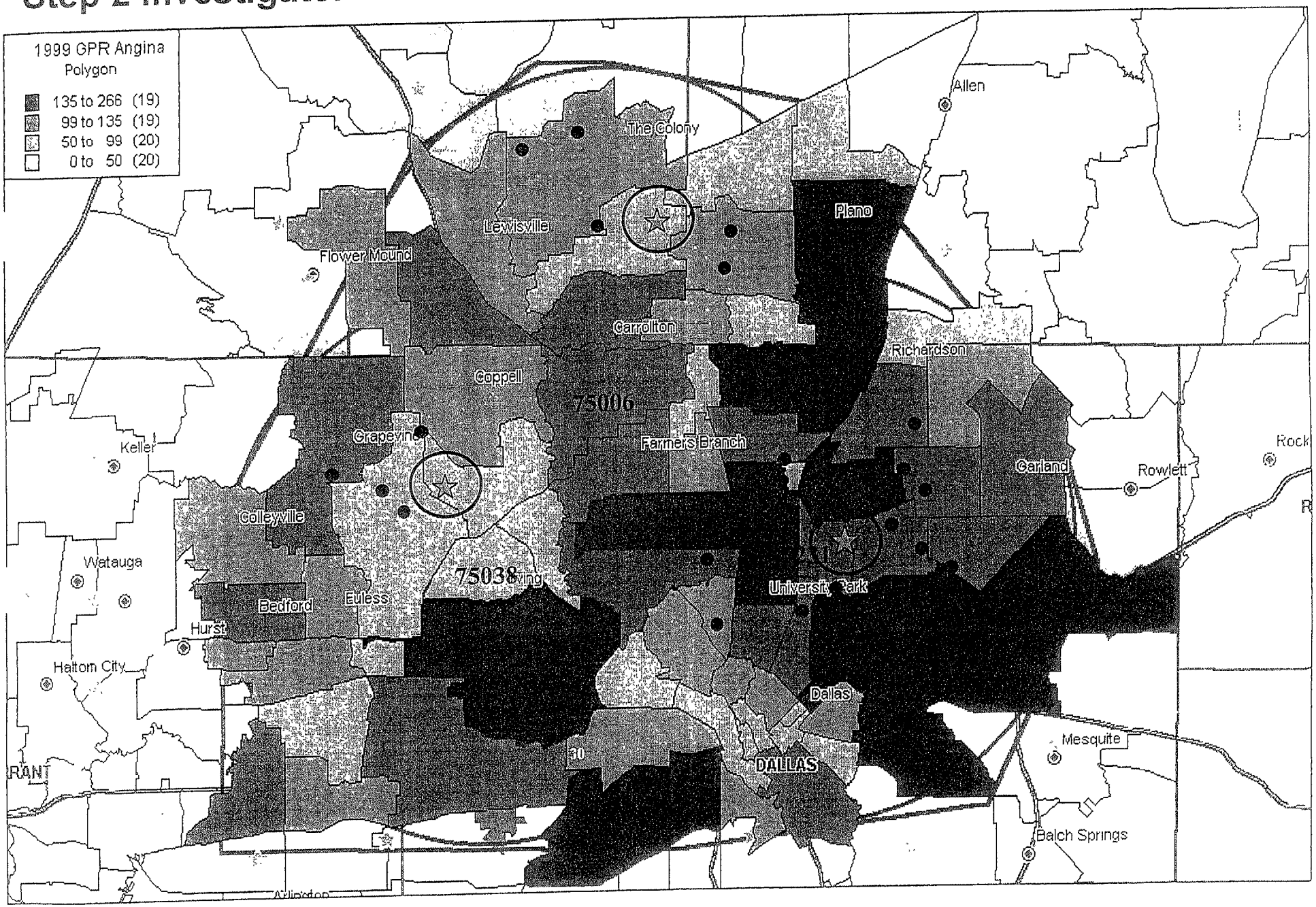
78/89

Step 1 Dallas – Fort Worth Area

Study – Angina

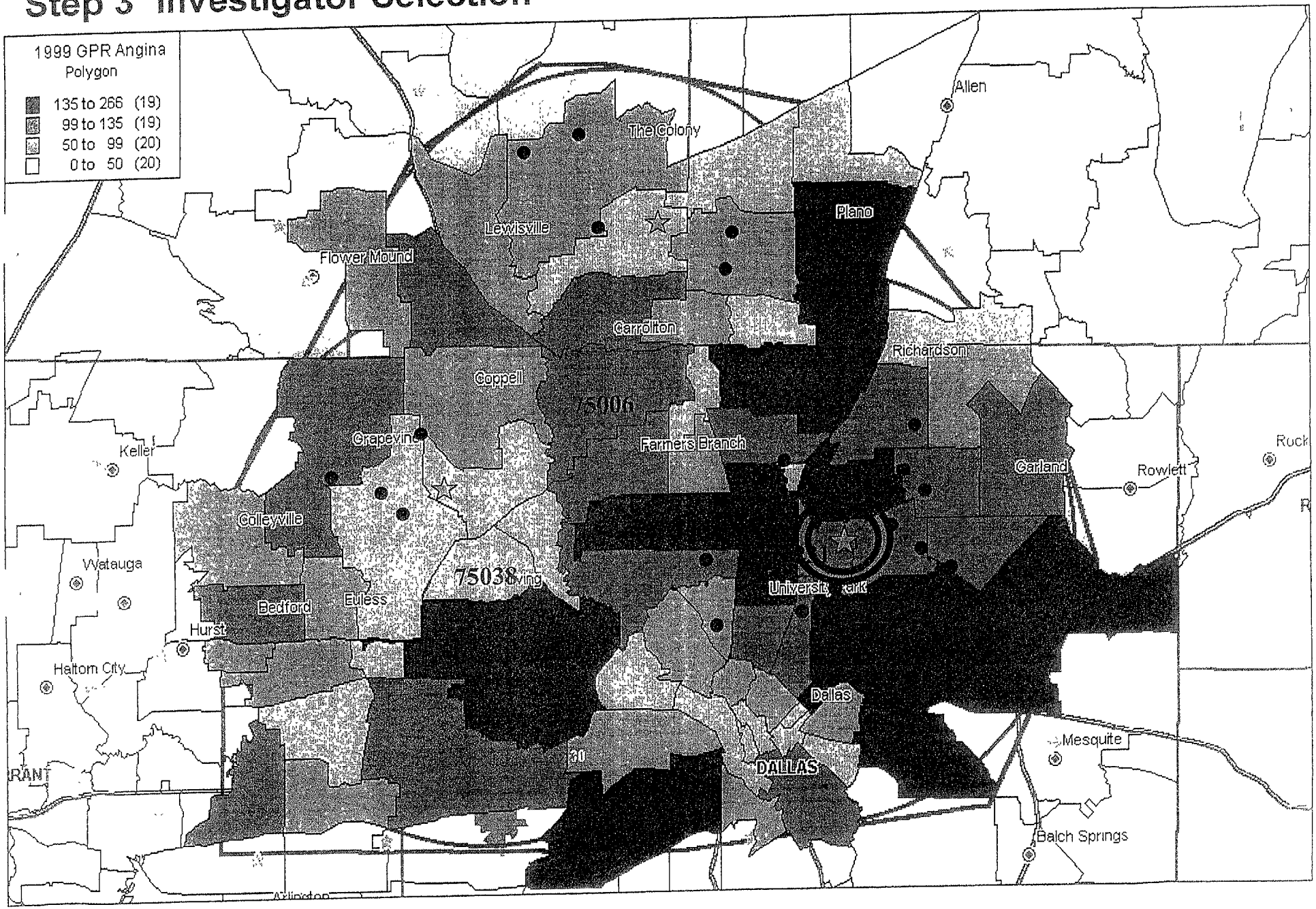


Step 2 Investigator Recruitment / Screening Case Study – Angina



Step 3 Investigator Selection

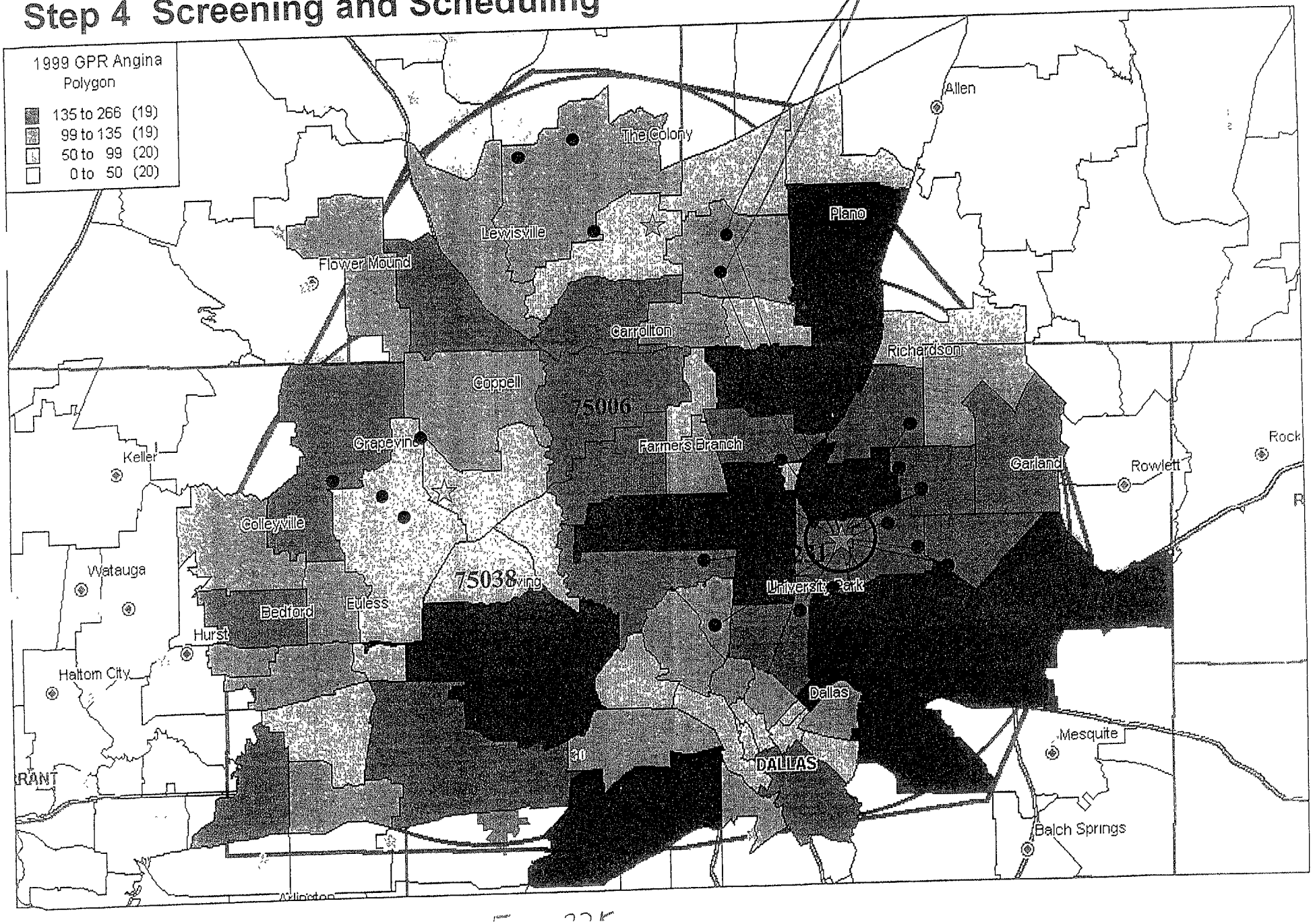
Case Study – Angina



Patient Sites

Step 4 Screening and Scheduling

Case Study – Angina



Smith, John

Specialty Cardiovascular Disease
Internal Medicine

CV

Contact Information | Primary Research Facility | Study Staff | Trial Experience | Provider | Hospital | Prismatic View

Yellow = ABC Pharma Trial

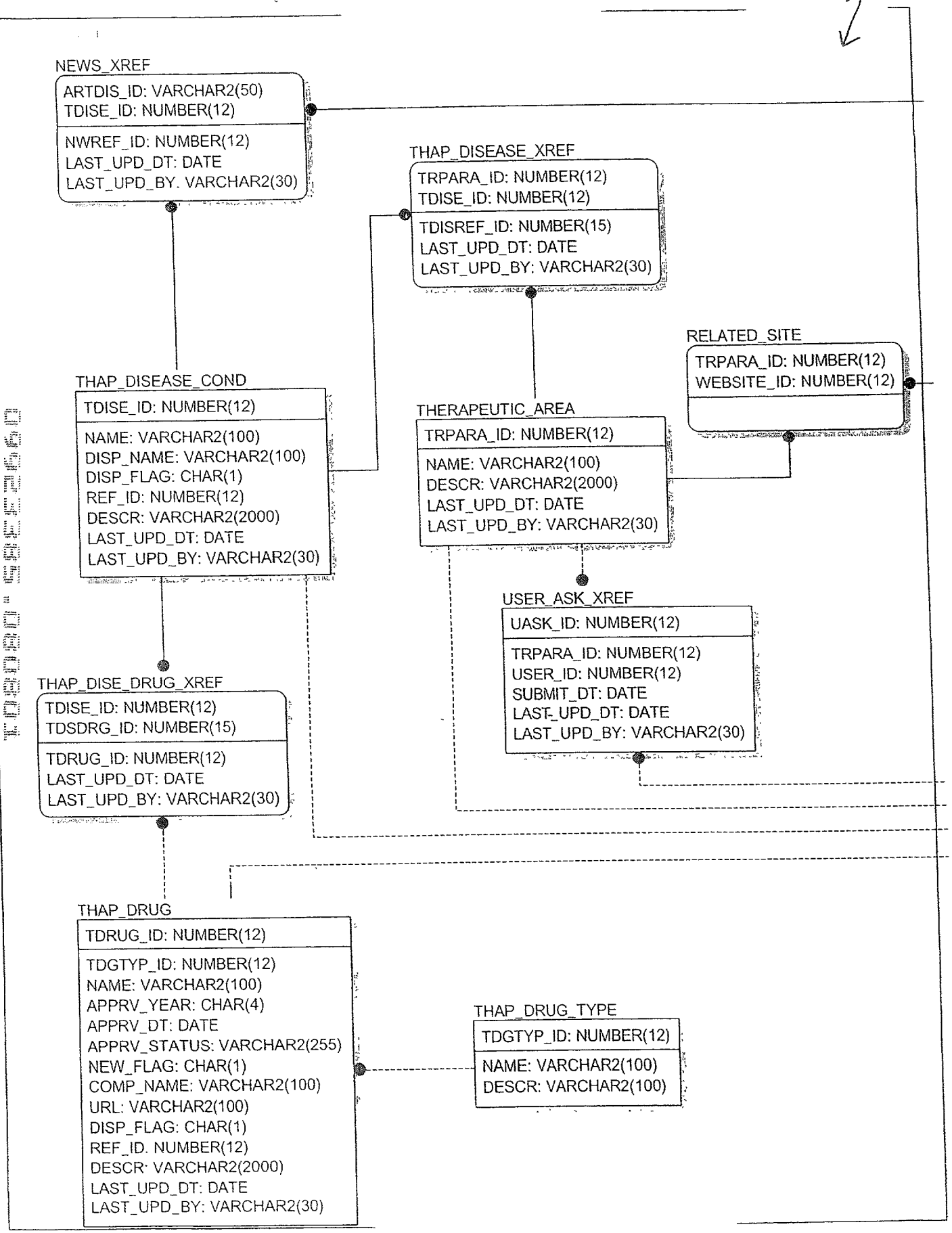
Indication	Start Date	Enrollment Commitment	Evaluable Patients	Timeframe (months)	Enrollment Percentage	ABC Pharma Rank
APT	1/15/2001	12	8	12	70%	4
CHF	11/1/2000	10	9	9	90%	
CHF	10/5/2000	10	9	9	90%	
CHD	7/1/2000	8	3	6	40%	2
CAD	6/1/1999	15	12	6	80%	
CHT	2/15/1999	8	7	10	90%	4
CHF	3/1/1998	10	8	12	80%	3
CHD	3/22/1997	6	4	10	60%	
CHD	6/1/1996	8	6	10	80%	

Aggregated data (2302)

Data supplied by sponsor viewing screen (2304)

Fig 23

2400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NWREF_ID: NUMBER(12)
LAST_UPD_DT: DATE
LAST_UPD_BY. VARCHAR2(30)
THAP_DISEASE_XREF
TRPARA_ID: NUMBER(12)
TDISE_ID: NUMBER(12)
TDISREF_ID: NUMBER(15)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
RELATED_SITE
TRPARA_ID: NUMBER(12)
WEBSITE_ID: NUMBER(12)
THAP_DISEASE_COND
TDISE_ID: NUMBER(12)
NAME: VARCHAR2(100)
DISP_NAME: VARCHAR2(100)
DISP_FLAG: CHAR(1)
REF_ID: NUMBER(12)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
THERAPEUTIC_AREA
TRPARA_ID: NUMBER(12)
NAME: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
USER_ASK_XREF
UASK_ID: NUMBER(12)
TRPARA_ID: NUMBER(12)
USER_ID: NUMBER(12)
SUBMIT_DT: DATE
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
THAP_DISE_DRUG_XREF
TDISE_ID: NUMBER(12)
TDSDRG_ID: NUMBER(15)
TDRUG_ID: NUMBER(12)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
THAP_DRUG
TDRUG_ID: NUMBER(12)
TDGTYP_ID: NUMBER(12)
NAME: VARCHAR2(100)
APPRV_YEAR: CHAR(4)
APPRV_DT: DATE
APPRV_STATUS: VARCHAR2(255)
NEW_FLAG: CHAR(1)
COMP_NAME: VARCHAR2(100)
URL: VARCHAR2(100)
DISP_FLAG: CHAR(1)
REF_ID. NUMBER(12)
DESCR· VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
THAP_DRUG_TYPE
TDGTYP_ID: NUMBER(12)
NAME: VARCHAR2(100)
DESCR: VARCHAR2(100)

Fig. 24A

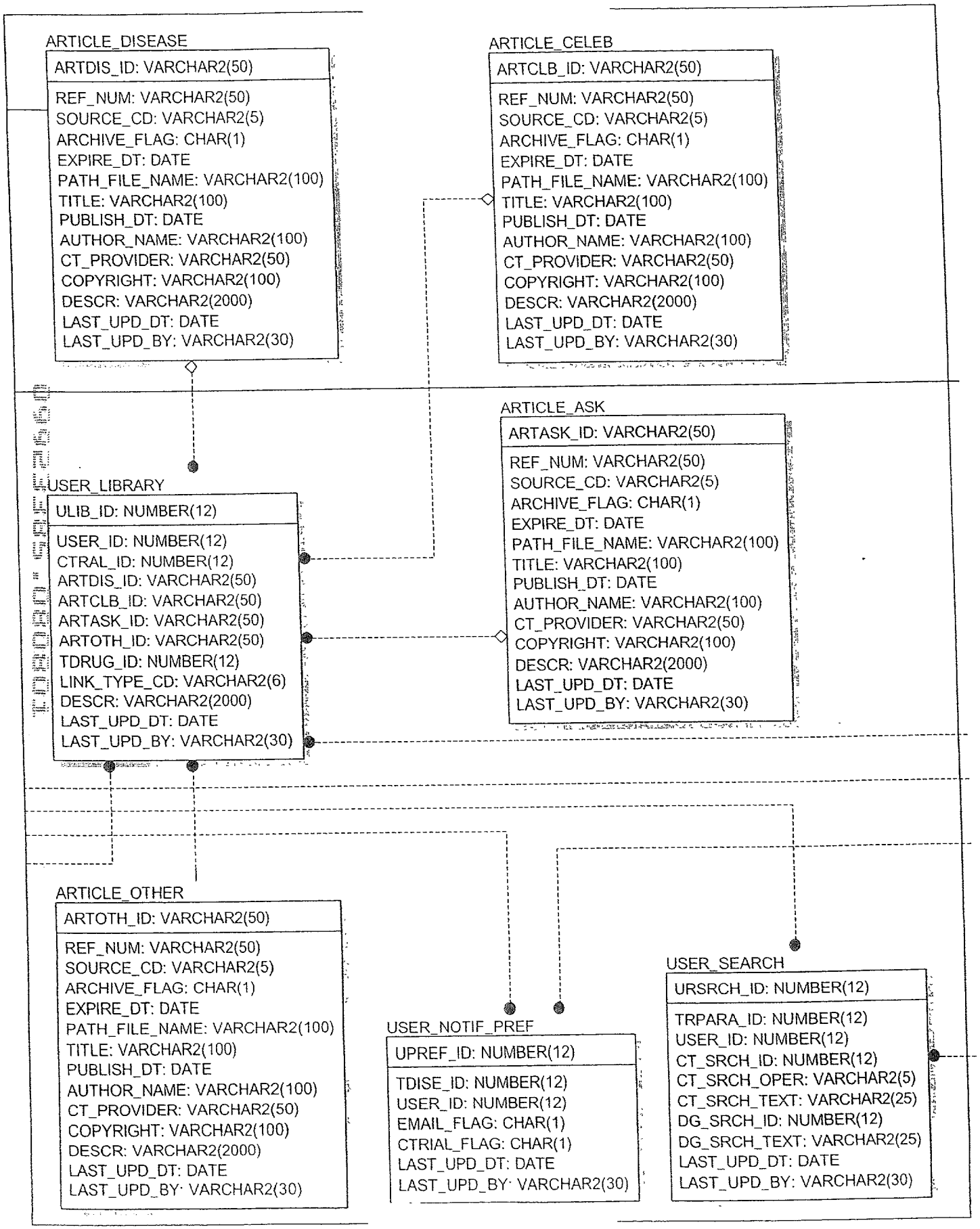
ARTICLE_DISEASE
ARTDIS_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ARTICLE_CELEB
ARTCLB_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ARTICLE_ASK
ARTASK_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
USER_LIBRARY
ULIB_ID: NUMBER(12)
USER_ID: NUMBER(12)
CTRAL_ID: NUMBER(12)
ARTDIS_ID: VARCHAR2(50)
ARTCLB_ID: VARCHAR2(50)
ARTASK_ID: VARCHAR2(50)
ARTOTH_ID: VARCHAR2(50)
TDRUG_ID: NUMBER(12)
LINK_TYPE_CD: VARCHAR2(6)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ARTICLE_OTHER
ARTOTH_ID: VARCHAR2(50)
REF_NUM: VARCHAR2(50)
SOURCE_CD: VARCHAR2(5)
ARCHIVE_FLAG: CHAR(1)
EXPIRE_DT: DATE
PATH_FILE_NAME: VARCHAR2(100)
TITLE: VARCHAR2(100)
PUBLISH_DT: DATE
AUTHOR_NAME: VARCHAR2(100)
CT_PROVIDER: VARCHAR2(50)
COPYRIGHT: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
USER_NOTIF_PREF
UPREF_ID: NUMBER(12)
TDISE_ID: NUMBER(12)
USER_ID: NUMBER(12)
EMAIL_FLAG: CHAR(1)
CTRIAL_FLAG: CHAR(1)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
USER_SEARCH
URSRCH_ID: NUMBER(12)
TRPARA_ID: NUMBER(12)
USER_ID: NUMBER(12)
CT_SRCH_ID: NUMBER(12)
CT_SRCH_OPER: VARCHAR2(5)
CT_SRCH_TEXT: VARCHAR2(25)
DG_SRCH_ID: NUMBER(12)
DG_SRCH_TEXT: VARCHAR2(25)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)

Fig. 24B

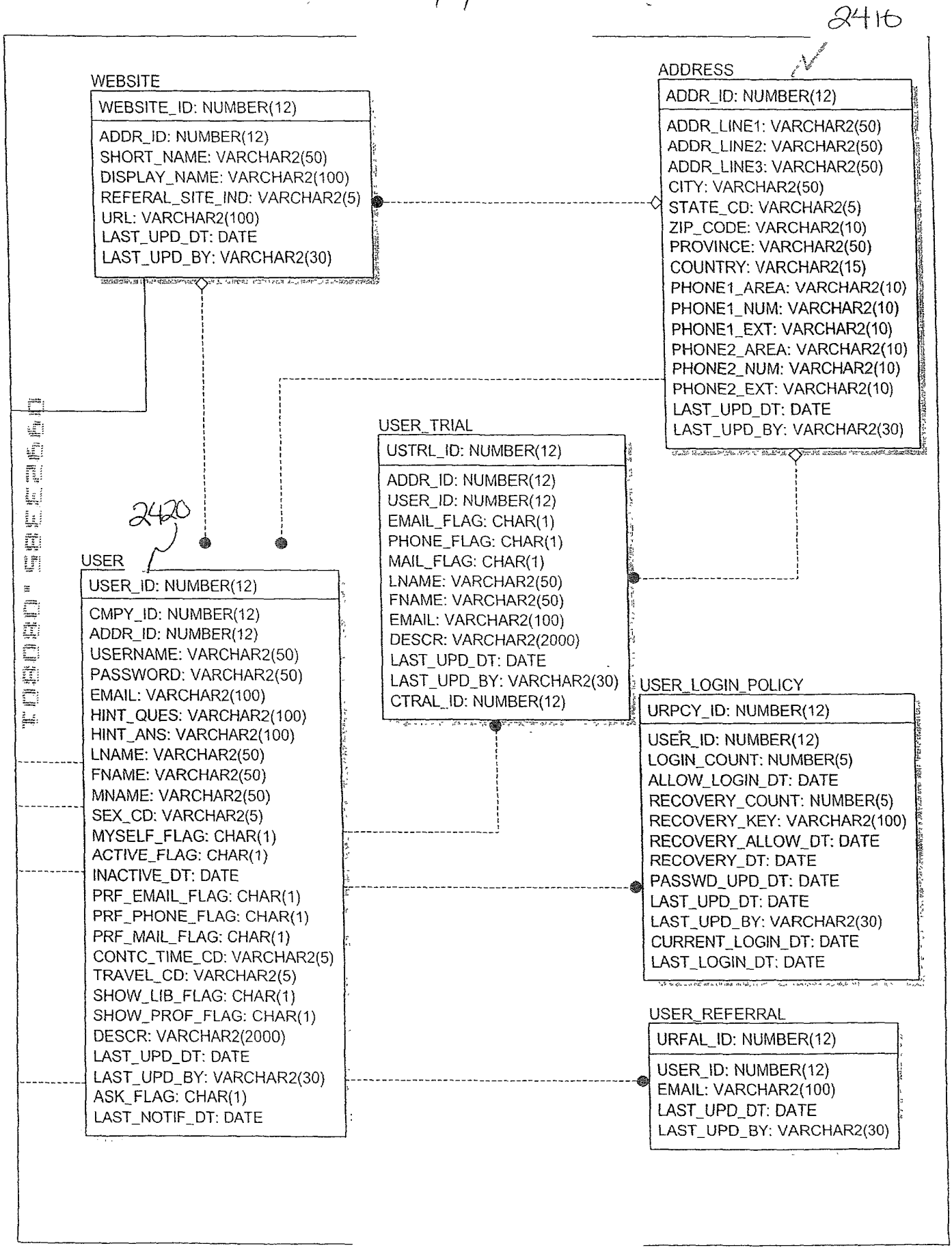
2410
WEBSITE
WEBSITE_ID: NUMBER(12)
ADDR_ID: NUMBER(12)
SHORT_NAME: VARCHAR2(50)
DISPLAY_NAME: VARCHAR2(100)
REFERAL_SITE_IND: VARCHAR2(5)
URL: VARCHAR2(100)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ADDRESS
ADDR_ID: NUMBER(12)
ADDR_LINE1: VARCHAR2(50)
ADDR_LINE2: VARCHAR2(50)
ADDR_LINE3: VARCHAR2(50)
CITY: VARCHAR2(50)
STATE_CD: VARCHAR2(5)
ZIP_CODE: VARCHAR2(10)
PROVINCE: VARCHAR2(50)
COUNTRY: VARCHAR2(15)
PHONE1_AREA: VARCHAR2(10)
PHONE1_NUM: VARCHAR2(10)
PHONE1_EXT: VARCHAR2(10)
PHONE2_AREA: VARCHAR2(10)
PHONE2_NUM: VARCHAR2(10)
PHONE2_EXT: VARCHAR2(10)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
USER_TRIAL
USTRL_ID: NUMBER(12)
ADDR_ID: NUMBER(12)
USER_ID: NUMBER(12)
EMAIL_FLAG: CHAR(1)
PHONE_FLAG: CHAR(1)
MAIL_FLAG: CHAR(1)
LNAME: VARCHAR2(50)
FNAME: VARCHAR2(50)
EMAIL: VARCHAR2(100)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
CTRAL_ID: NUMBER(12)
2420
USER
USER_ID: NUMBER(12)
CMPY_ID: NUMBER(12)
ADDR_ID: NUMBER(12)
USERNAME: VARCHAR2(50)
PASSWORD: VARCHAR2(50)
EMAIL: VARCHAR2(100)
HINT_QUES: VARCHAR2(100)
HINT_ANS: VARCHAR2(100)
LNAME: VARCHAR2(50)
FNAME: VARCHAR2(50)
MNAME: VARCHAR2(50)
SEX_CD: VARCHAR2(5)
MYSELF_FLAG: CHAR(1)
ACTIVE_FLAG: CHAR(1)
INACTIVE_DT: DATE
PRF_EMAIL_FLAG: CHAR(1)
PRF_PHONE_FLAG: CHAR(1)
PRF_MAIL_FLAG: CHAR(1)
CONTC_TIME_CD: VARCHAR2(5)
TRAVEL_CD: VARCHAR2(5)
SHOW_LIB_FLAG: CHAR(1)
SHOW_PROF_FLAG: CHAR(1)
DESCR: VARCHAR2(2000)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
ASK_FLAG: CHAR(1)
LAST_NOTIF_DT: DATE
USER_LOGIN_POLICY
URPCY_ID: NUMBER(12)
USER_ID: NUMBER(12)
LOGIN_COUNT: NUMBER(5)
ALLOW_LOGIN_DT: DATE
RECOVERY_COUNT: NUMBER(5)
RECOVERY_KEY: VARCHAR2(100)
RECOVERY_ALLOW_DT: DATE
RECOVERY_DT: DATE
PASSWD_UPD_DT: DATE
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)
CURRENT_LOGIN_DT: DATE
LAST_LOGIN_DT: DATE
USER_REFERRAL
URFAL_ID: NUMBER(12)
USER_ID: NUMBER(12)
EMAIL: VARCHAR2(100)
LAST_UPD_DT: DATE
LAST_UPD_BY: VARCHAR2(30)

Fig. 24C

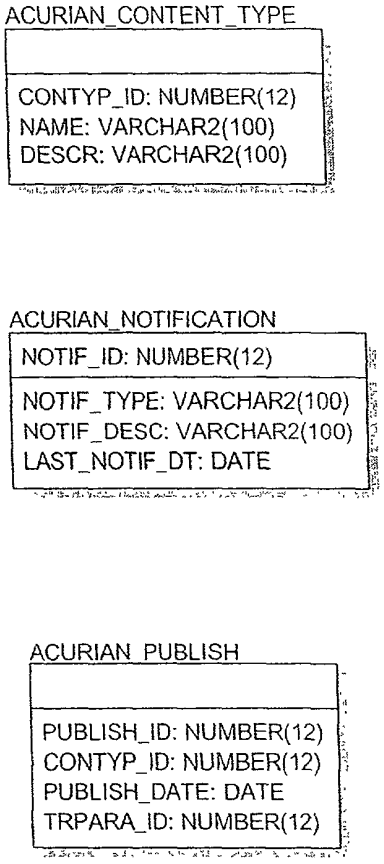

Fig. 24D

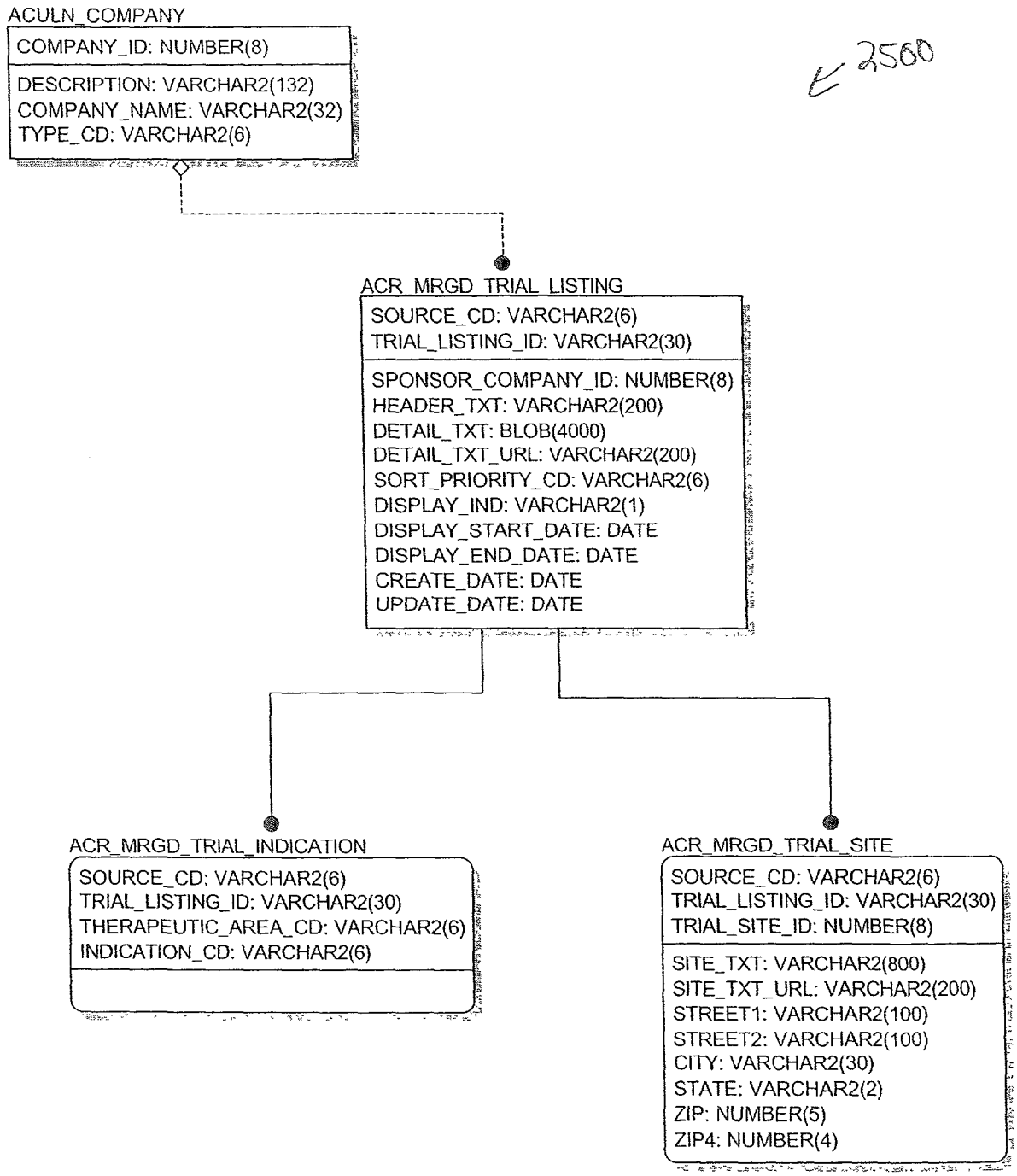
ACULN_COMPANY
COMPANY_ID: NUMBER(8)
DESCRIPTION: VARCHAR2(132)
COMPANY_NAME: VARCHAR2(32)
TYPE_CD: VARCHAR2(6)
2560
ACR_MRGD_TRIAL_LISTING
SOURCE_CD: VARCHAR2(6)
TRIAL_LISTING_ID: VARCHAR2(30)
SPONSOR_COMPANY_ID: NUMBER(8)
HEADER_TXT: VARCHAR2(200)
DETAIL_TXT: BLOB(4000)
DETAIL_TXT_URL: VARCHAR2(200)
SORT_PRIORITY_CD: VARCHAR2(6)
DISPLAY_IND: VARCHAR2(1)
DISPLAY_START_DATE: DATE
DISPLAY_END_DATE: DATE
CREATE_DATE: DATE
UPDATE_DATE: DATE
ACR_MRGD_TRIAL_INDICATION
SOURCE_CD: VARCHAR2(6)
TRIAL_LISTING_ID: VARCHAR2(30)
THERAPEUTIC_AREA_CD: VARCHAR2(6)
INDICATION_CD: VARCHAR2(6)
ACR_MRGD_TRIAL_SITE
SOURCE_CD: VARCHAR2(6)
TRIAL_LISTING_ID: VARCHAR2(30)
TRIAL_SITE_ID: NUMBER(8)
SITE_TXT: VARCHAR2(800)
SITE_TXT_URL: VARCHAR2(200)
STREET1: VARCHAR2(100)
STREET2: VARCHAR2(100)
CITY: VARCHAR2(30)
STATE: VARCHAR2(2)
ZIP: NUMBER(5)
ZIP4: NUMBER(4)

Fig. 25

maticView

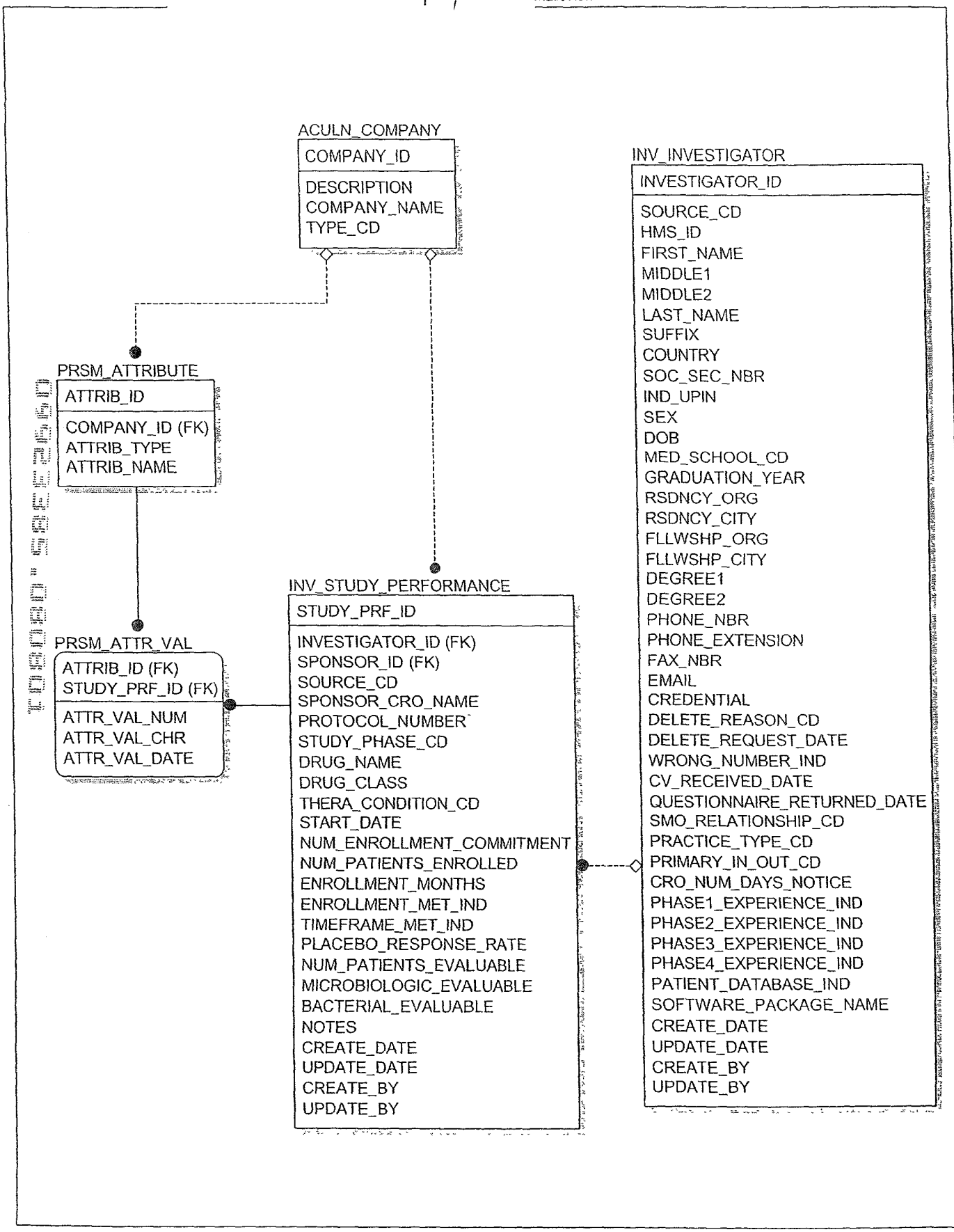

Fig. 26

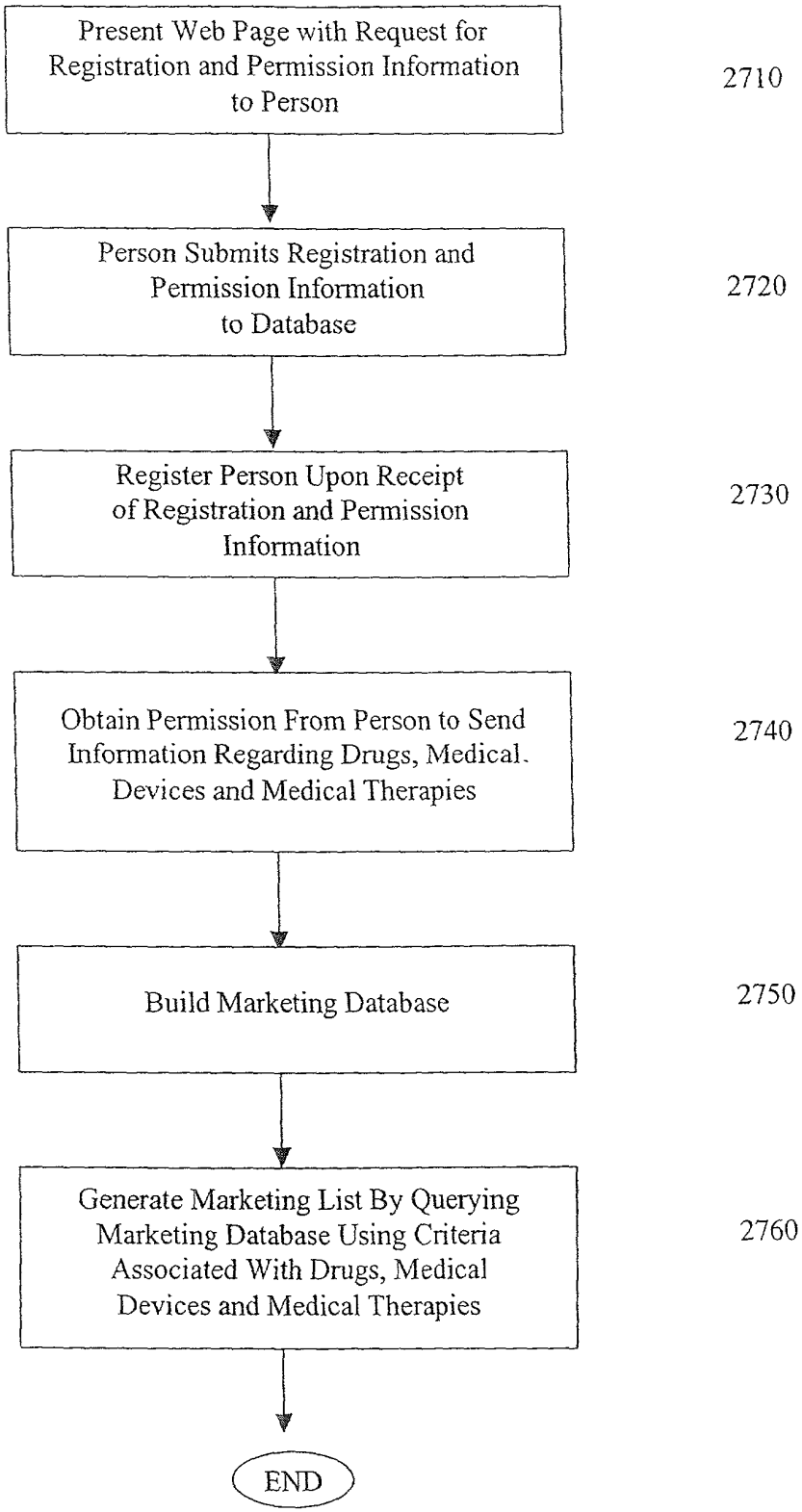
Present Web Page with Request for Registration and Permission Information to Person
2710
Person Submits Registration and Permission Information to Database
2720
Register Person Upon Receipt of Registration and Permission Information
2730
Obtain Permission From Person to Send Information Regarding Drugs, Medical Devices and Medical Therapies
2740
Build Marketing Database
2750
Generate Marketing List By Querying Marketing Database Using Criteria Associated With Drugs, Medical Devices and Medical Therapies
2760
END

FIG. 27